## Reference Committee E

**Report(s) of the Council on Science and Public Health**

01 Council on Science and Public Health Sunset Review of 2015 House Policies
05 Screening for Image Manipulation in Research Publications
08 Explainability of Artificial/Augmented Intelligence and Machine Learning Algorithms
09 Rare Disease Advisory Councils

**Resolutions**

501 Safer Button / Coin Batteries
502 NIH Grant Funding for Medical Research
503 Safeguarding Neural Data Collected by Neurotechnologies
504 Physician Performed Microscopy Designation for Synovial Fluid Crystal Exam: Modify the Clinical Laboratory Amendment of 1988
505 Mandating Properly Fitting Lead Aprons in Hospitals
506 Opposing the use of harm reduction items as evidence of commercial sex work
507 Clinical and Public Safety Implications of AI-Generated Content and Symbolic Compliance Infrastructure
508 Standardizing Safety Requirements for Traditional and Rideshare-Based Non-Emergency Medical Transportation
509 Allergen Labeling for Spices and Herbs
510 Improving Cybersecurity Standards for Healthcare Entities
511 Increased Transparency Among Psychotropic Drug Administration in Prisons
512 Preventing Drug-Facilitated Sexual Assault in Drinking Establishments
513 Transparency on Comparative Effectiveness in Direct-to-Consumer Advertising
514 Support for a Nicotine Free Generation
515 Nitrous Oxide Abuse
516 Creating a Registry of Potential Side Effects of GIP & GLP-1 Medications
517 In Support of a National Drug Checking Registry
518 Mandatory Accreditation and Regular Inspections of Hyperbaric Chambers
519 Framework to Convey Evidence-Based Medicine in AI Tools Used in Clinical Decision Making
520 Study of Grading Systems in AMA Board Reports
521 Warning labels on OTC sleep aids
522 Access to Important and Essential Drugs

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 1-A-25

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| Subject: | Council on Science and Public Health Sunset Review of 2015 House Policies |
| Presented by: | John T. Carlo, MD, MS, Chair |
| Referred to: | Reference Committee E |

Policy G-600.110, "Sunset Mechanism for AMA Policy," calls for the decennial review of American Medical Association (AMA) policies to ensure that our AMA's policy database is current, coherent, and relevant. This policy reads as follows, laying out the parameters for review and specifying the needed procedures:

1. As the House of Delegates adopts policies, a maximum 10-year time horizon shall exist. A policy will typically sunset after ten years unless action is taken by the House of Delegates to retain it. Any action of our AMA House that reaffirms or amends an existing policy position shall reset the sunset "clock," making the reaffirmed or amended policy viable for another 10 years.

2. In the implementation and ongoing operation of our AMA policy sunset mechanism, the following procedures shall be followed: (a) Each year, the Speakers shall provide a list of policies that are subject to review under the policy sunset mechanism; (b) Such policies shall be assigned to the appropriate AMA councils for review; (c) Each AMA council that has been asked to review policies shall develop and submit a report to the House of Delegates identifying policies that are scheduled to sunset; (d) For each policy under review, the reviewing council can recommend one of the following actions: (i) retain the policy; (ii) sunset the policy; (iii) retain part of the policy; or (iv) reconcile the policy with more recent and like policy; (e) For each recommendation that it makes to retain a policy in any fashion, the reviewing council shall provide a succinct, but cogent justification (f) The Speakers shall determine the best way for the House of Delegates to handle the sunset reports.

3. Nothing in this policy shall prohibit a report to the HOD or resolution to sunset a policy earlier than its 10-year horizon if it is no longer relevant, has been superseded by a more current policy, or has been accomplished.

4. The AMA councils and the House of Delegates should conform to the following guidelines for sunset: (a) when a policy is no longer relevant or necessary; (b) when a policy or directive has been accomplished; or (c) when the policy or directive is part of an established AMA practice that is transparent to the House and codified elsewhere such as the AMA Bylaws or the AMA House of Delegates Reference Manual: Procedures, Policies and Practices.

5. The most recent policy shall be deemed to supersede contradictory past AMA policies.
6. Sunset policies will be retained in the AMA historical archives.

RECOMMENDATION

The Council on Science and Public Health recommends that the House of Delegates policies listed in the appendix to this report be acted upon in the manner indicated and the remainder of this report be filed. (Directive to Take Action)

Fiscal Note: $1,000.

APPENDIX: RECOMMENDED ACTIONS

| Policy Number | Title | Text | Recommendation |
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| D-100.998 | Combating Antibiotic Resistance Via Physician Action and Education: AMA Activities | Our AMA will continue to collaborate with the appropriate federal agencies, other medical specialty societies, and other appropriate public health organizations to address the urgent problem of increasing antimicrobial resistance and its impact on public health. | Retain, still relevant. |
| D-120.953 | Treatment of Opioid Dependence | Our AMA will work to end the limitation of 100 patients per certified physician treating opioid dependence after the second year of treatment as currently mandated by the Drug Addiction Treatment Act. | Rescind. This requirement has been removed with the removal of the X-Waiver requirement. |
| D-120.975 | Preserving Patients? Ability to Have Legally Valid Prescriptions Filed | Our AMA will:<br><br>(1) work with state medical societies to support legislation to protect patients? ability to have legally valid prescriptions filled;<br><br>(2) enter into discussions with relevant associations (including but not limited to the American Hospital Association, American Pharmacists Association, American Society of Health System Pharmacists, National Association of Chain Drug Stores, and National Community Pharmacists Association) to guarantee that, if an individual pharmacist exercises a conscientious refusal to dispense a legal prescription, a patient's right to obtain legal prescriptions will be protected by immediate referral to an appropriate dispensing pharmacy; and<br><br>(3) in the absence of all other remedies, work with state medical societies to adopt state legislation that will allow physicians to dispense medication to their own patients when there is no pharmacist within a thirty-mile radius who is able and willing to dispense that medication. | Retain as amended.<br><br>**Preserving Patients'~~?~~ Ability to Have Legally Valid Prescriptions Filled**<br>Our AMA will:<br><br>(1) work with state medical societies to support legislation to protect patients'~~?~~ ability to have legally valid prescriptions filled;<br><br>(2) ~~enter into discussions~~ work with relevant associations (including but not limited to the American Hospital Association, American Pharmacists Association, American Society of Health System Pharmacists, National Association of Chain Drug Stores, and National Community Pharmacists Association) to guarantee that, if an individual pharmacist exercises a conscientious refusal to dispense a legal prescription, a patient's right to obtain legal prescriptions will be protected by immediate referral to an appropriate dispensing pharmacy; and<br><br>(3) in the absence of all other remedies, work with state medical societies to adopt state legislation that will allow physicians to dispense |

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| | | | medication to their own patients when there is no pharmacist within a thirty-mile radius who is able and willing to dispense that medication. |
| D-120.979 | DEA Regulations and the Ability of Physicians to Prescribe Controlled Medication Rationally, Safely, and Without Undue Threat of Prosecution | Our AMA supports ongoing constructive dialogue between the DEA and clinicians, including physicians, regarding a proper balance between the needs of patients for treatment and the needs of the government to provide oversight and regulation to minimize risks to public health and safety. | Retain, convert to H-policy. |
| D-130.966 | Domestic Disaster Relief Funding | 1. Our American Medical Association lobby Congress to a) reassess its policy for expedited release of funding to disaster areas; b) define areas of disaster with disproportionate indirect and direct consequences of disaster as "public health emergencies"; and c) explore a separate, less bureaucratic process for providing funding and resources to these areas in an effort to reduce morbidity and mortality post-disaster.<br><br>2. Our AMA will lobby actively for the recommendations outlined in the AMA/APHA Linkages Leadership Summit including: a) appropriate funding and protection of public health and health care systems as critical infrastructures for responding to day-to-day emergencies and mass causality events; b) full integration and interoperable public health and health care disaster preparedness and response systems at all government levels; c) adequate legal protection in a disaster for public health and healthcare responders and d) incorporation of disaster preparedness and response competency-based education and training in undergraduate, graduate, post-graduate, and continuing education programs. | Retain as amended to remove outdated language (i.e. there is now a statutory definition of "public health emergency" that is not aligned to this recommendation) and references (AMA/APHA Linkages Leadership Summit) and convert to an H-policy.<br><br>1. Our American Medical Association lobby Congress to ~~a)~~ reassess its policy for expedited release of funding to disaster areas as well as a~~; b) define areas of disaster with disproportionate indirect and direct consequences of disaster as "public health emergencies"; and c) explore a separate,~~ less bureaucratic process for providing funding and resources to these areas in an effort to reduce morbidity and mortality post-disaster.<br><br>2. Our AMA will lobby actively for ~~the recommendations outlined in the AMA/APHA Linkages Leadership Summit including~~: a) appropriate funding and protection of public health and health care systems as critical infrastructures for responding to day-to-day emergencies and mass causality events; b) full integration and interoperable public health and health care disaster preparedness and response systems at all |

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| | | | government levels; c) adequate legal protection in a disaster for public health and healthcare responders and d) incorporation of disaster preparedness and response competency-based education and training in undergraduate, graduate, post-graduate, and continuing education programs. |
| D-130.972 | All Hazards Disaster Preparedness and Response | Our AMA will work with: (1) subject matter experts at the national level to quickly produce a provider manual on state licensure and medical liability coverage for physicians during disasters; (2) appropriate medical, public health, disaster response and relief organizations to improve plans, protocols, and policies regarding the provision of health care in mass evacuation shelters; and (3) appropriate state and local organizations to develop templates for private practice/office continuity plans in CD-ROM or web-based format that can be stored in state medical association offices on a server in the event of a disaster. | Retain as amended to reflect completed directives and convert to an H-policy.<br><br>Our AMA encourages ~~will work with: (1) subject matter experts at the national level to quickly produce the creation of a provider manual on state licensure and medical liability coverage for physicians during disasters; (2)~~ appropriate medical, public health, disaster response and relief organizations to improve plans, protocols, and policies regarding the provision of health care in mass evacuation shelters ~~and (3) appropriate state and local organizations to develop templates for private practice/office continuity plans in CD-ROM or web-based a format that can be stored in state medical association offices on a server in the event of a disaster~~. |
| D-135.971 | Evaluation of Canadian Underground Nuclear Waste Repository | Our American Medical Association, along with state and county medical societies, will urge Congress, the President, and the Secretary of State to invoke the participation of the International Joint Commission to evaluate the proposed underground nuclear waste repository in Ontario, Canada, and similar facilities. | Retain, still relevant. |
| D-135.972 | Support Reduction of Carbon Dioxide Emissions | Our AMA will (1) inform the President of the United States, the Administrator of the Environmental Protection Agency (EPA), and Congress that our American Medical Association supports the Administration's efforts to limit carbon dioxide emissions from power plants to protect public health; and (2) working with state medical societies, encourage state governors to support and comply with | Retain as amended to rescind the directive that has been accomplished and convert to an H-policy.<br><br>Our AMA ~~will (1) inform the President of the United States, the Administrator of the~~ |

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| | | EPA regulations designed to limit carbon dioxide emissions from coal fired power plants. | ~~Environmental Protection Agency (EPA), and Congress that our American Medical Association~~ support ~~the Administration's~~ efforts to limit carbon dioxide emissions from power plants to protect public health; and (2) ~~working with~~ in collaboration with state medical societies, encourages state governors to support and comply with EPA regulations designed to limit carbon dioxide emissions from coal fired power plants. |
| D-145.996 | Preventing Firearm-Related Injury and Morbidity in Youth | Our American Medical Association will identify and support the distribution of firearm safety materials that are appropriate for the clinical setting. | Retain, still relevant. |
| D-170.994 | School Health Mentoring Program | Our AMA (1) encourages the Centers for Disease Control and Prevention (CDC) and other appropriate federal agencies to support the development of school health mentoring programs for allopathic and osteopathic volunteer physicians to work with teachers to educate children in grades K through 4 on the importance of good health habits; and (2) will work in collaboration with the Federation to lobby the US Congress for funds to teach early childhood health education in schools. | Retain, still relevant. |
| D-30.995 | Increasing Taxes on Alcoholic Beverages | Our AMA will: (1) support increases in federal taxes on beer, wine, and liquor, with a substantial portion of the new revenues to be earmarked to the prevention of alcohol abuse and drunken driving, treatment of persons with alcohol use disorders or at-risk drinking patterns, and public health and medical programs that serve vulnerable populations; (2) encourage state and local increases in taxes on beer, wine, and liquor, with a substantial portion of the new revenues to be earmarked to the purposes noted above; (3) support, to the extent possible, state and local efforts to increase taxes on beer, wine, and liquor; (4) collaborate with other national organizations with an interest in this subject, including national medical specialty societies, the American Public Health Association, the Center for Science in the Public Interest, Mothers Against Drunk Driving, and the AMA Alliance; and (5) when state legislative efforts to increase alcohol taxes are stymied, encourage state medical societies to give consideration to the use of ballot initiatives in the states that allow such initiatives. | Retain as amended to update language and convert to an H-policy.<br><br>Our AMA ~~will~~: (1) supports increases in federal taxes on beer, wine, and liquor, with a substantial portion of the new revenues to be earmarked to the prevention of alcohol misuse ~~abuse~~ and ~~drunken~~ driving while intoxicated, treatment of persons with alcohol use disorders or at-risk drinking patterns, and public health and medical programs that serve vulnerable populations; (2) encourages state and local increases in taxes on beer, wine, and liquor, with a substantial portion of the new revenues to be earmarked to the purposes noted above; (3) supports, to the extent possible, state and local efforts to increase taxes on beer, wine, and liquor; (4) |

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| | | | supports collaboration ~~collaborate~~ with other national organizations with an interest in this subject, including national medical specialty societies, the American Public Health Association, the Center for Science in the Public Interest, Mothers Against Drunk Driving, and the AMA Alliance; and (5) when state legislative efforts to increase alcohol taxes are stymied, encourages state medical societies to give consideration to the use of ballot initiatives in the states that allow such initiatives. |
| D-30.997 | Eliminate Underage Alcohol Consumption | Our AMA will support evidence-based public health/environmental policies to curtail destructive and high-risk drinking. | Retain as amended to update language and convert to an H-policy.<br><br>Our AMA ~~will~~ supports evidence-based public health ~~/~~ and ~~and~~ environmental policies to curtail ~~destructive and~~ high-risk drinking. |
| D-350.985 | Addressing Sexual Violence and Improving American Indian and Alaska Native Women's Health Outcomes | 1. Our AMA advocates for mitigation of the critical issues of American Indian/Alaska Native women's health that place Native women at increased risk for sexual violence, and encourages allocation of sufficient resources to the clinics serving this population to facilitate health care delivery commensurate with the current epidemic of violence against Native women.<br>2. Our AMA will collaborate with the Indian Health Service, Centers for Disease Control and Prevention (CDC), Tribal authorities, community organizations, and other interested stakeholders to develop programs to educate physicians and other health care professionals about the legal and cultural contexts of their American Indian and Alaska Native female patients as well as the current epidemic of violence against Native women and the pursuant medical needs of this population.<br>3. Our AMA will collaborate with the Indian Health Service, CDC, Tribal authorities, and community organizations to obtain or develop appropriate American Indian and Alaska Native women's health materials for distribution to patients in the spirit of self-determination to improve responses to sexual violence and overall health outcomes. | Retain, still relevant. |
| D-440.931 | Encourage Autism Society to Support Vaccinations | Our American Medical Association will work jointly with the American College of Physicians, American Academy of Pediatrics and American Academy of Family Physicians to encourage the Autism Society of | Rescind, this directive has been accomplished.<br>Other existing AMA policies including H-440.830, |

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| | | America to display on their website that based on current scientific evidence, autism is not caused by vaccinations and encourage vaccinations to promote better health for all our population. | "Education and Public Awareness on Vaccine Safety and Efficacy," recognize the substantial body of scientific evidence that has disproven a link between vaccines and autism. |
| D-440.932 | Preventing Allergic Reactions in Food Service Establishments | Our American Medical Association will pursue federal legislation requiring restaurants and food establishments to: (1) include a notice in menus reminding customers to let the staff know of any food allergies; (2) educate their staff regarding common food allergens and the need to remind customers to inform wait staff of any allergies; and (3) identify menu items which contain any of the major food allergens identified by the FDA (in the Food Allergen Labeling and Consumer Protection Act of 2004) and which allergens the menu item contains. | Retain as amended and convert to H-policy.<br><br>Our American Medical Association supports~~will pursue~~ federal legislation requiring restaurants and food establishments to: (1) include a notice in menus reminding customers to let the staff know of any food allergies; (2) educate their staff regarding common food allergens and the need to remind customers to inform wait staff of any allergies; and (3) identify menu items which contain any of the major food allergens identified by the FDA (in the Food Allergen Labeling and Consumer Protection Act of 2004) and which allergens the menu item contains. |
| D-440.944 | Disease Transmission Via Foods: Public Health Disaster in Waiting | Our AMA: (1) publicly calls for enhancement of the protocols, authority, oversight and funding, as well as encourages public health leadership at the federal agencies charged with regulation of the food industry and maintenance of a safer food supply and will monitor the success of such efforts. | Retain, still relevant. |
| D-440.961 | Establishment of a Network of State Immunization Registries | Our AMA will work with the Centers for Disease Control and Prevention, the Department of Health and Human Services, the Public Health Service and other interested organizations to develop a network of state-based immunization registries that meet a set of minimum standards and allow for access at a national level, while ensuring the protection of the patient-physician relationship. | Retain, still relevant. |
| D-45.998 | Reducing the Risk of Flight-Associated Venous Thrombosis | Our AMA will continue to monitor research on developments concerning the relationship between air travel and venous thromboembolism and respond appropriately when more definitive results become available, and urges the Federal Aviation Administration and individual airlines to provide more comprehensive educational modalities detailing DVT prevention for all long-duration domestic and international airline flights. | Retain, still relevant. |

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| D-460.980 | Scientific Integrity | Our AMA advocates the federal government should rely on sound medical science in formulating public health policies. | Retain, still relevant. |
| D-510.994 | Health Care for Veterans and Their Families | Our AMA will: (1) work with all appropriate medical societies, the AMA National Advisory Council on Violence and Abuse, and government entities to assist with the implementation of all recommendations put forth by the President's Commission on Care for America's Wounded Warriors; and (2) advocate for improved access to medical care in the civilian sector for returning military personnel when their needs are not being met by resources locally available through the Department of Defense or the Veterans Administration. | Rescind. The AMA National Advisory Council on Violence and Abuse no longer exists and specific elements of the policy, such as expansion of insurance benefits, recruitment of clinical staff, and support of PTSD and/or TBI research, are captured in other existing AMA policies, such as H-510.985, "Access to Health Care for Veterans," H-510.986, "Ensuring Access to Safe and Quality Care for our Veterans," D-510.990, "Fixing the VA Physician Shortage with Physicians," and H-510.988, "Supporting Awareness of Stress Disorders in Military Members and Their Families." |
| D-65.995 | Health Disparities Among Gay, Lesbian, Bisexual, Transgender and Queer Families | Our AMA supports reducing the health disparities suffered because of unequal treatment of minor children and same sex parents in same sex households by supporting equality in laws affecting health care of members in same sex partner households and their dependent children. | Retain as amended to update language, convert to H-policy.<br><br>Our AMA supports reducing the health disparities suffered because of unequal treatment of minor children and ~~same sex parents in same sex households~~ their parents in LGBTQ households by supporting equality in laws affecting health care of ~~members~~ LGBTQ families ~~in same sex partner households and their dependent children~~. |
| H-10.962 | Encouraging Protocols to Assist with the Management of Patients with Obesity During Positioning and Transportation | Our American Medical Association encourages health care professionals to learn about techniques and devices to prevent potential injury and to provide safe and effective care for patients with obesity. | Retain, still relevant. |
| H-10.986 | Use of Non-Toxic Aversive Additives | The AMA (1) in conjunction with other professional organizations, encourages individual manufacturers to consider adding non-toxic aversive products to either existent or newly introduced formulations when such have been deemed as having significant toxic potentials in order to provide safety in poison prevention; (2) believes that such actions should be publicized as intended to augment, but in no way | Retain, still relevant. |

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| | | replace, other poison prevention programs such as child-resistant containers, appropriate packaging and labeling, parental education, etc; and (3) supports continuing efforts by the household products and drug industries to identify methods of reducing the incidence of accidental poisonings. | |
| H-100.952 | Enhancing Antibiotic Stewardship in the Human Health Care Setting to Improve Patient Outcomes | Our AMA will: (1) support antimicrobial stewardship programs, overseen by qualified physicians, as an effective way to ensure appropriate antibiotic use to reduce the burden of antimicrobial resistance, to improve patient outcomes, and to reduce overall costs for health care facilities and systems. Antibiotic stewardship programs are systematic, multi-faceted, patient safety programs, and use evidence-based approaches to optimize antibiotic prescribing, encompassing components such as policy, guidelines, surveillance, education, epidemiology, process, and outcome measurement. Successful antibiotic stewardship programs monitor and direct antimicrobial use, providing a standard, evidence-based approach to judicious antibiotic use across the spectrum of care, including, but not limited to acute care hospitals, outpatient clinics, emergency departments and long-term care facilities; (2) support the development of antibiotic stewardship programs that allow flexibility so that adherence to national requirements does not limit the ability of providers to design programs based on local variables, such as health care facility size, patient population served, and care delivery setting (e.g., outpatient v. inpatient) and to address local antimicrobial stewardship and infection prevention challenges; (3) urge each health care facility's governing body to promote and support robust, physician-led antimicrobial stewardship and infection prevention programs as critical components of assuring safe patient care; and (4) support continued research into the impact of antibiotic stewardship programs on process outcomes and encourage increased research on the impact of such programs on patient-centered outcomes. | Retain, still relevant. |
| H-100.953 | Establishment of Limited Population Antibacterial Drug Approval Pathway | 1. Our AMA supports establishment of the Limited Population Antibacterial Drug (LAPD) mechanism to provide a predictable and feasible Food and Drug Administration approval pathway for pharmaceutical companies seeking to develop antibacterial drugs to treat serious and life-threatening infections where there is a lack of sufficient or satisfactory therapeutic options through legislative or regulatory means.<br>2. Should the LPAD be established, our AMA shall work with the Infectious Diseases Society of America, other medical societies, and the health care community to educate providers about LPAD products, including their benefits and risks. | Retain as amended with a change in title with recognition that LPAD has been established.<br><br>~~Establishment of~~ Limited Population Antibacterial Drug Approval Pathway<br><br>1. Our AMA supports ~~establishment of~~ the Limited Population Antibacterial Drug LPAD ~~LAPD~~) mechanism ~~to~~ which provides a predictable and feasible Food and Drug Administration approval |

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| | | | pathway for pharmaceutical companies seeking to develop antibacterial drugs to treat serious and life-threatening infections where there is a lack of sufficient or satisfactory therapeutic options through legislative or regulatory means.<br>2. ~~Should the LPAD be established, our~~ Our AMA shall work with the Infectious Diseases Society of America, other medical societies, and the health care community to educate providers about LPAD products, including their benefits and risks. |
| H-100.960 | The 10 x '20 Initiative (10 New Antibiotics by 2020) | Our AMA: (1) supports efforts to educate physicians, the Administration, Congress, and the public about the problem of antimicrobial resistance and the lack of new antibiotics in the drug development pipeline; and (2) endorses the 10 x '20 Initiative (10 new antibiotics by 2020) and supports efforts to bring together experts from the industrial, medical, scientific, policy, regulatory, and financial communities to determine and adopt the right combination of incentives needed to create a sustainable antibiotic research and development enterprise. | Retain as amended with a change in title.<br><br>~~The 10 x '20 Initiative (10~~ Incentivizing New Antibiotics ~~by 2020)~~<br><br>Our AMA: (1) supports efforts to educate physicians, the Administration, Congress, and the public about the problem of antimicrobial resistance and the lack of new antibiotics in the drug development pipeline; and (2) ~~endorses the 10 x '20 Initiative (10 new antibiotics by 2020) and~~ supports efforts to bring together experts from the industrial, medical, scientific, policy, regulatory, and financial communities to determine and adopt the right combination of incentives needed to create a sustainable antibiotic research and development enterprise. |
| H-100.971 | Preserving the Doctor-Patient Relationship | The AMA and interested physicians will continue to work with the Food and Drug Administration to prevent the unnecessary intrusion of the government and other regulatory bodies into the doctor-patient relationship, especially as it concerns the prescription of medication. | Retain, still relevant. |
| H-100.973 | Combating Antimicrobial Resistance through Education | Our AMA: (1) encourages the federal government, the World Health Organization, the World Medical Association, and the International Federation of Pharmacists to promote more effective education | Retain as amended to update relevant language as the "International Federation of Pharmacists" is now the |

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| | | concerning the appropriate use of antibiotics;<br><br>(2) strongly urges physicians to educate their patients about their antimicrobial therapy, the importance of compliance with the prescribed regimen, and the problem of antimicrobial resistance;<br><br>(3) will continue to educate physicians and physicians-in-training about the appropriate prescribing of antimicrobial agents;<br><br>(4) encourages the use of antibiotic resistance management programs; these education-based programs should be multidisciplinary and cooperative (i.e., including infectious disease physicians, infection-control specialists, microbiology laboratory personnel, and clinical pharmacists); and<br><br>(5) encourages continued scientific research on the issue of antibiotic resistance. | "International Pharmaceutical Federation."<br><br>Our AMA: (1) encourages the federal government, the World Health Organization, the World Medical Association, and the International Pharmaceutical Federation ~~of Pharmacists~~ to promote more effective education concerning the appropriate use of antibiotics;<br><br>(2) strongly urges physicians to educate their patients about their antimicrobial therapy, the importance of compliance with the prescribed regimen, and the problem of antimicrobial resistance;<br><br>(3) will continue to educate physicians and physicians-in-training about the appropriate prescribing of antimicrobial agents;<br><br>(4) encourages the use of antimicrobial~~biotic~~ resistance management programs; these education-based programs should be multidisciplinary and cooperative (i.e., including infectious disease physicians, infection-control specialists, microbiology laboratory personnel, and clinical pharmacists); and<br><br>(5) encourages continued scientific research on the issue of antimicrobial~~biotic~~ resistance. |
| H-115.967 | Addressing Drug Overdose and Patient Compliance with Targeted Pharmaceutical Packaging Efforts | Our American Medical Association supports research into, and development of, novel and affordable pharmaceutical packaging for dispensed medications, as well as abuse deterrent formulations in attempts to increase ease of use, improve patient adherence, and decrease the potential for misuse and abuse of controlled substances. | Retain as amended to update language with a change in title.<br><br>Addressing Drug Overdose and Patient Adherence ~~Compliance~~ with Targeted Pharmaceutical Packaging Efforts<br><br>Our American Medical Association supports research |

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| | | | into, and development of, novel and affordable pharmaceutical packaging for dispensed medications, as well as abuse deterrent formulations in attempts to increase ease of use, improve patient adherence, and decrease the potential for the misuse ~~and abuse~~ of controlled substances. |
| H-115.971 | Safety and Efficacy of Selective Serotonin Reuptake Inhibitors (SSRIs) in Children and Adolescents | Our AMA recognizes that the current product labeling (package insert) of antidepressant drugs, including the Black Box warnings, is a precautionary statement intended to reinforce the need for careful monitoring of patients with depression and other psychiatric disorders during the initiation of treatment. This product labeling should not be interpreted in a way that would decrease access for patients who may benefit from these drugs. | Retain, still relevant. |
| H-115.983 | Expiration Dates and Beyond-Use Dates of Prescription and Over-the-Counter Drug Products | Our AMA: (1) supports the inclusion of expiration dates on the containers/labels of prescription and over-the-counter drug products and recommends that expiration dates be determined by pharmaceutical manufacturers using scientifically based stability testing with subsequent approval by the Food and Drug Administration (FDA); (2) urges the pharmaceutical industry, in collaboration with purchasers, the FDA, and the United States Pharmacopeia (USP), to determine whether lengthening of expiration dates will provide clinical and/or economic benefits or risks for patients and, if this is the case, to conduct longer stability testing on their drug products; (3) urges the FDA to work with the pharmaceutical industry and the USP to develop a schedule for the review and re-evaluation of expiration dates of prescription and over-the-counter drug products; (4) recommends that pharmacists place a beyond-use date on the labeling of all prescription medications dispensed to patients, and that the beyond-use date be based on the recommendations in the most recent edition of the United States Pharmacopeia and National Formulary; and (5) encourages the USP, in collaboration with pharmaceutical manufacturers, pharmacy organizations, and the FDA, to continue to explore the development of appropriate stability tests for the determination of scientifically sound beyond-use dates for repackaged products. | Retain, still relevant. |
| H-115.994 | Prescription Product Labeling | 1. The official labeling should not be regarded as the sole standard of acceptable or accepted medical practice nor as a substitute for clinical judgment or experience nor as a limitation on usage of the drug in medical practice. The official labeling statements approved by the FDA establish the parameters | Retain, still relevant. |

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| | | governing advertising or promotion of the drug product.<br><br>2. Our AMA will advocate that the FDA work to establish a process whereby the official drug labeling can be updated in a more expeditious fashion when new evidence becomes available affecting the clinical use of prescription medications and that evidence-based standards or peer-reviewed medical literature can add to legacy information contained in official drug labeling statements to guide drug administration and usage. | |
| H-120.956 | Internet Prescribing | Our AMA will: (1) support the use of the Internet as a mechanism to prescribe medications with appropriate safeguards to ensure that the standards for high quality medical care are fulfilled; (2) work with state medical societies in urging state medical boards to ensure high quality medical care by investigating and, when appropriate, taking necessary action against physicians who fail to meet the local standards of medical care when issuing prescriptions through Internet web sites that dispense prescription medications; (3) work with the Federation of State Medical Boards and others in endorsing or developing model state legislation to establish limitations on Internet prescribing; (4) continue to work with the National Association of Boards of Pharmacy and support their "Verified Internet Pharmacy Practice Sites" program so that physicians and patients can easily identify legitimate Internet pharmacy practice sites; (5) work with federal and state regulatory bodies to close down Internet web sites of companies that are illegally promoting and distributing (selling) prescription drug products in the United States; and (6) keep pace with changes in technology by continually updating standards of practice on the Internet. | Retain as amended to update language. The National Association of Boards of Pharmacy use a different term to describe their accreditation.<br><br>Our AMA will: (1) support the use of the Internet as a mechanism to prescribe medications with appropriate safeguards to ensure that the standards for high quality medical care are fulfilled; (2) work with state medical societies in urging state medical boards to ensure high quality medical care by investigating and, when appropriate, taking necessary action against physicians who fail to meet the local standards of medical care when issuing prescriptions through Internet web sites that dispense prescription medications; (3) work with the Federation of State Medical Boards and others in endorsing or developing model state legislation to establish limitations on Internet prescribing; (4) continue to work with the National Association of Boards of Pharmacy and support their digital pharmacy accreditation ~~"Verified Internet Pharmacy Practice Sites"~~ program so that physicians and patients can easily identify legitimate Internet pharmacy practice sites; (5) work with federal and state regulatory bodies to close down Internet web sites |

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| | | | of companies that are illegally promoting and distributing (selling) prescription drug products in the United States; and (6) keep pace with changes in technology by continually updating standards of practice on the Internet. |
| H-120.965 | Medication Errors | The AMA reaffirms its long-standing supportive efforts to curtail the problems of medication errors; and encourages physicians to add a brief notation of purpose (e.g., for cough, for constipation) on prescriptions, where appropriate, to avoid confusion on the part of either the pharmacists or the patients. | Retain, still relevant. |
| H-130.942 | Development of a Federal Public Health Disaster Intervention Team | 1. Our AMA supports government efforts to: (a) coordinate and integrate federal medical and public health disaster response entities such as the Medical Reserve Corps, National Disaster Medical System, Public Health Services Commissioned Corps (PHSCC), as well as state-to-state sponsored Emergency Management Compact Systems, to strengthen health system infrastructure and surge capacity for catastrophic disasters (Incidents of National Significance) as defined by the Department of Homeland Security's (DHS) National Response Plan (NRP); and (b) place all federal medical and public health disaster response assets (with the exception of the Department of Defense) under authority of the Secretary of the Department of Health and Human Services (DHHS) to prevent significant delays and ensure coordination during a catastrophic disaster (Incident of National Significance).<br><br>2. Our AMA, through its Center for Public Health Preparedness and Disaster Response, will work with the DHHS, PHSCC, DHS, and other relevant government agencies to provide comprehensive disaster education and training for all federal medical and public health employees and volunteers through the National Disaster Life Support and other appropriate programs. Such training should address the medical and mental health needs of all populations, including children, the elderly, and other vulnerable groups.<br><br>3. Our AMA, through its Center for Public Health Preparedness and Disaster Response, will monitor progress in strengthening federal disaster medical and public health response capacity for deployment anywhere in the nation on short notice, and report back as appropriate. | Retain as amended to remove reference to the AMA's Center for Public Health Preparedness & Disaster Response and related work, which has ended.<br><br>1. Our AMA supports government efforts to: (a) coordinate and integrate federal medical and public health disaster response entities such as the Medical Reserve Corps, National Disaster Medical System, Public Health Services Commissioned Corps (PHSCC), as well as state-to-state sponsored Emergency Management Compact Systems, to strengthen health system infrastructure and surge capacity for catastrophic disasters (Incidents of National Significance) as defined by the Department of Homeland Security's (DHS) National Response Plan (NRP); and (b) place all federal medical and public health disaster response assets (with the exception of the Department of Defense) under authority of the Secretary of the Department of Health and Human Services (DHHS) to prevent significant delays and ensure coordination during a catastrophic disaster (Incident of National Significance). |

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| | | | ~~2. Our AMA, through its Center for Public Health Preparedness and Disaster Response, will work with the DHHS, PHSCC, DHS, and other relevant government agencies to provide comprehensive disaster education and training for all federal medical and public health employees and volunteers through the National Disaster Life Support and other appropriate programs. Such training should address the medical and mental health needs of all populations, including children, the elderly, and other vulnerable groups~~.<br><br>~~3~~ 2. Our AMA~~, through its Center for Public Health Preparedness and Disaster Response,~~ will monitor progress in strengthening federal disaster medical and public health response capacity for deployment anywhere in the nation on short notice, and report back as appropriate. |
| H-130.946 | AMA Leadership in the Medical Response to Terrorism and Other Disasters | Our AMA: (1) Condemns terrorism in all its forms and provide leadership in coordinating efforts to improve the medical and public health response to terrorism and other disasters.<br><br>(2) Will work collaboratively with the Federation in the development, dissemination, and evaluation of a national education and training initiative, called the National Disaster Life Support Program, to provide physicians, medical students, other health professionals, and other emergency responders with a fundamental understanding and working knowledge of their integrated roles and responsibilities in disaster management and response efforts.<br><br>(3) Will join in working with the Department of Homeland Security, the Department of Health and Human Services, the Department of Defense, the Federal Emergency Management Agency, and other appropriate federal agencies; state, local, and medical specialty societies; other health care associations; and private foundations to (a) ensure adequate resources, supplies, and training to enhance the medical and public health response to terrorism and other disasters; | Retain as amended to remove an initiative the AMA is no longer involved in.<br><br>Our AMA: (1) Condemns terrorism in all its forms and provides leadership in coordinating efforts to improve the medical and public health response to terrorism and other disasters.<br><br>(2) ~~Will work collaboratively with the Federation in the development, dissemination, and evaluation of a national education and training initiative, called the National Disaster Life Support Foundation Program,~~ supports efforts to provide physicians, medical students, other health professionals, and other emergency responders with a |

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| | | (b) develop a comprehensive strategy to assure surge capacity to address mass casualty care; (c) implement communications strategies to inform health care professionals and the public about a terrorist attack or other major disaster, including local information on available medical and mental health services; (d) convene local and regional workshops to share "best practices" and "lessons learned" from disaster planning and response activities; (e) organize annual symposia to share new scientific knowledge and information for enhancing the medical and public health response to terrorism and other disasters; and (f) develop joint educational programs to enhance clinical collaboration and increase physician knowledge of the diagnosis and treatment of depression, anxiety, and post traumatic stress disorders associated with exposure to disaster, tragedy, and trauma.<br><br>(4) Believes all physicians should (a) be alert to the occurrence of unexplained illness and death in the community; (b) be knowledgeable of disease surveillance and control capabilities for responding to unusual clusters of diseases, symptoms, or presentations; (c) be knowledgeable of procedures used to collect patient information for surveillance as well as the rationale and procedures for reporting patients and patient information; (d) be familiar with the clinical manifestations, diagnostic techniques, isolation precautions, decontamination protocols, and chemotherapy/prophylaxis of chemical, biological, and radioactive agents likely to be used in a terrorist attack; (e) utilize appropriate procedures to prevent exposure to themselves and others; (f) prescribe treatment plans that may include management of psychological and physical trauma; (g) understand the essentials of risk communication so that they can communicate clearly and nonthreateningly with patients, their families, and the media about issues such as exposure risks and potential preventive measures (e.g., smallpox vaccination); and (h) understand the role of the public health, emergency medical services, emergency management, and incident management systems in disaster response and the individual health professional's role in these systems.<br><br>(5) Believes that physicians and other health professionals who have direct involvement in a mass casualty event should be knowledgeable of public health interventions that must be considered following the onset of a disaster including: (a) quarantine and other movement restriction options; (b) mass immunization/chemoprophylaxis; (c) mass triage; (d) public education about preventing or reducing exposures; (e) environmental decontamination and | fundamental understanding and working knowledge of their integrated roles and responsibilities in disaster management and response efforts.<br><br>(3) Will join in working with the Department of Homeland Security, the Department of Health and Human Services, the Department of Defense, the Federal Emergency Management Agency, and other appropriate federal agencies; state, local, and medical specialty societies; other health care associations; and private foundations to (a) ensure adequate resources, supplies, and training to enhance the medical and public health response to terrorism and other disasters; (b) develop a comprehensive strategy to assure surge capacity to address mass casualty care; (c) implement communications strategies to inform health care professionals and the public about a terrorist attack or other major disaster, including local information on available medical and mental health services; (d) convene local and regional workshops to share "best practices" and "lessons learned" from disaster planning and response activities; (e) organize annual symposia to share new scientific knowledge and information for enhancing the medical and public health response to terrorism and other disasters; and (f) develop joint educational programs to enhance clinical collaboration and increase physician knowledge of the diagnosis and treatment of depression, anxiety, and post traumatic stress disorders associated with exposure to disaster, tragedy, and trauma. |

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| | | sanitation; (f) public health laws; and (g) state and federal resources that contribute to emergency management and response at the local level.<br><br>(6) Believes that physicians and other health professionals should be knowledgeable of ethical and legal issues and disaster response. These include: (a) their professional responsibility to treat victims (including those with potentially contagious conditions); (b) their rights and responsibilities to protect themselves from harm; (c) issues surrounding their responsibilities and rights as volunteers, and (d) associated liability issues.<br><br>(7) Believes physicians and medical societies should participate directly with state, local, and national public health, law enforcement, and emergency management authorities in developing and implementing disaster preparedness and response protocols in their communities, hospitals, and practices in preparation for terrorism and other disasters.<br><br>(8) Urges Congress to appropriate funds to support research and development (a) to improve understanding of the epidemiology, pathogenesis, and treatment of diseases caused by potential bioweapon agents and the immune response to such agents; (b) for new and more effective vaccines, pharmaceuticals, and antidotes against biological and chemical weapons; (c) for enhancing the shelf life of existing vaccines, pharmaceuticals, and antidotes; and (d) for improving biological chemical, and radioactive agent detection and defense capabilities. | (4) Believes all physicians should (a) be alert to the occurrence of unexplained illness and death in the community; (b) be knowledgeable of disease surveillance and control capabilities for responding to unusual clusters of diseases, symptoms, or presentations; (c) be knowledgeable of procedures used to collect patient information for surveillance as well as the rationale and procedures for reporting patients and patient information; (d) be familiar with the clinical manifestations, diagnostic techniques, isolation precautions, decontamination protocols, and chemotherapy/prophylaxis of chemical, biological, and radioactive agents likely to be used in a terrorist attack; (e) utilize appropriate procedures to prevent exposure to themselves and others; (f) prescribe treatment plans that may include management of psychological and physical trauma; (g) understand the essentials of risk communication so that they can communicate clearly and nonthreateningly with patients, their families, and the media about issues such as exposure risks and potential preventive measures (e.g., smallpox vaccination); and (h) understand the role of the public health, emergency medical services, emergency management, and incident management systems in disaster response and the individual health professional's role in these systems.<br><br>(5) Believes that physicians and other health professionals who have direct involvement |

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| | | | in a mass casualty event should be knowledgeable of public health interventions that must be considered following the onset of a disaster including: (a) quarantine and other movement restriction options; (b) mass immunization/chemoprophylaxis; (c) mass triage; (d) public education about preventing or reducing exposures; (e) environmental decontamination and sanitation; (f) public health laws; and (g) state and federal resources that contribute to emergency management and response at the local level.<br><br>(6) Believes that physicians and other health professionals should be knowledgeable of ethical and legal issues and disaster response. These include: (a) their professional responsibility to treat victims (including those with potentially contagious conditions); (b) their rights and responsibilities to protect themselves from harm; (c) issues surrounding their responsibilities and rights as volunteers, and (d) associated liability issues.<br><br>(7) Believes physicians and medical societies should participate directly with state, local,<br>and national public health, law enforcement, and emergency management authorities in developing and implementing disaster preparedness and response protocols in their communities, hospitals, and practices in preparation for terrorism and other disasters.<br><br>(8) Urges Congress to appropriate funds to support research and development (a) to improve understanding of the epidemiology, |

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| | | | pathogenesis, and treatment of diseases caused by potential bioweapon agents and the immune response to such agents; (b) for new and more effective vaccines, pharmaceuticals, and antidotes against biological and chemical weapons; (c) for enhancing the shelf life of existing vaccines, pharmaceuticals, and antidotes; and (d) for improving biological chemical, and radioactive agent detection and defense capabilities. |
| H-130.952 | Community-Wide Training in Basic Life Support and First Aid | Our AMA: (1) encourages education in (a) basic life support and first aid, and (b) effective interventions for reducing and preventing injuries and coronary heart disease; (2) urges state and local medical societies to participate in the development and promotion of community programs for adults, children, businesses, community groups, and public servants to increase awareness of the potential benefits of training in basic life support and first aid and to increase public knowledge, confidence, and motivation for responding to serious, or potentially serious illness and injury situations; and (3) encourages physicians to discuss with their patients: (a) how to recognize and respond to emergency situations; (b) proper utilization and activation of the local EMS system; (c) measures for reducing or eliminating potential risk factors for injuries and coronary heart disease; and (d) the availability and appropriateness of community programs in basic life support and first aid. | Retain, still relevant. |
| H-135.929 | Banning Plastic Microbeads in Personal Care Products | Our AMA supports local, state, and federal laws banning the sale and manufacture of personal care products containing plastic microbeads. | Retain, still relevant. |
| H-135.930 | Protecting Public Health from Natural Gas Infrastructure | Our AMA recognizes the potential impact on human health associated with natural gas infrastructure and supports legislation that would require a comprehensive Health Impact Assessment regarding the health risks that may be associated with natural gas pipelines. | Retain, still relevant. |
| H-135.955 | Human Health and the Protection of Biodiversity | The AMA urges physicians and other health care professionals and the public to become more aware of the importance of protecting biological diversity and its relationship to human health. | Retain, still relevant. |
| H-135.989 | Low Level Radioactive Waste Disposal | The AMA (1) believes that each state should be responsible for providing capacity within or outside the state for disposal of commercial, non-military low level radioactive waste generated within its border; | Retain, still relevant. |

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| | | and (2) urges Environmental Protection Agency action to ensure capacity for disposal of low level radioactive waste. | |
| H-145.974 | Increasing Toy Gun Safety | Our American Medical Association (1) encourages toy gun manufacturers to take further steps beyond the addition of an orange tip on the gun to reduce the similarity of toy guns with real guns, and (2) encourages parents to increase their awareness of toy gun ownership risks. | Retain, still relevant. |
| H-15.949 | Auto Heat Deaths | Our American Medical Association supports efforts to reduce deaths of children left in unattended vehicles. | Retain, still relevant. |
| H-15.960 | Motor Vehicle and Bicycle Safety | The AMA supports legislation that would make safety belt non-use by any occupants in automobiles and other enclosed motor vehicles a "primary offense" in all states; supports extension of motorcycle helmet laws to include motorized vehicles such as mopeds, scooters and all-terrain vehicles, and to cover all age groups; and supports legislation that would require helmet usage for riders of bicycles, including passengers. | Retain, still relevant. |
| H-15.988 | Modification of Three-Point Shoulder Harness Seat Belt to Enable Use by Small Children | The AMA (1) recognizes the value of using appropriately designed three-point safety belt restraints to reduce auto-related injuries and fatalities; (2) supports auto industry modifications in restraints for safe use by children and small adults; and (3) supports the development of standards required for such modifications by appropriate authorities. | Retain, still relevant. |
| H-150.941 | Banning the Use of Artificial Trans Fat in the United States | Our AMA supports state and federal legislation that bans the use of artificial trans fats in the United States. | Retain, still relevant. |
| H-150.947 | Mercury and Fish Consumption: Medical and Public Health Issues | AMA policy is that: (1) Women who might become pregnant, are pregnant, or who are nursing should follow federal, state or local advisories on fish consumption. Because some types of fish are known to have much lower than average levels of methylmercury and can be safely consumed more often and in larger amounts, women should also seek specific consumption recommendations from those authorities regarding locally caught or sold fish. (2) Physicians should (a) assist in educating patients about the relative mercury content of fish and shellfish products; (b) make patients aware of the advice contained in both national and regional consumer fish consumption advisories; and (c) have sample materials available, or direct patients to where they can access information on national and regional fish consumption advisories. (3) Testing of the mercury content of fish should be continued by appropriate agencies; results should be publicly accessible and reported in a consumer-friendly format. | Retain, still relevant. |
| H-150.959 | Risk of Transmission of Bovine Spongiform Encephalopathy to | The AMA: (1) supports the current FDA guidance/regulations regarding the treatment of products from bovine sources destined for human utilization, and the treatment of blood products from potential Creutzfeld-Jakob disease (CJD) donors; (2) | The AMA: (1) supports the current FDA guidance/regulations regarding the treatment of products from bovine sources destined for |

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| | Humans in the United States | recommends the FDA and the United States Department of Agriculture (USDA) continue to aggressively enforce regulations in place to prevent the occurrence/transmission of bovine spongiform encephalopathy (BSE) in the United States; (3) recommends the FDA, USDA, and Department of Health and Human Services continue to evaluate scientific data on transmissible spongiform encephalopathies (TSEs) and incorporate this information into their guidance and regulations; (4) recommends increased surveillance of new CJD cases as they arise in order to monitor for the possible appearance of new variant Creutzfeldt-Jakob disease (nv-CJD) via: (a) Referral of all deaths due to suspected CJD to an appropriately qualified pathologist for autopsy, with the submission of autopsy reports of confirmed cases to the Prion Disease Pathology Surveillance Center at Case Western Reserve University, which is collaborating with the CDC. (b) Reporting of the diagnosis of CJD on the death certificate in all cases and the strengthening of the current system enabling health authorities to obtain clinical or pathologic data on the CJD cases of greatest public health concern. (c) Prompt notification of any case of new variant Creutzfeldt-Jakob disease to both the appropriate state health department and the CDC; and (5) recommends that well-controlled research be performed in the following areas: (a) Elucidation of the mechanism of disease of TSEs; (b) Elucidation of the infectivity, dose requirements, and clearance of the disease agent to provide more data for adequate risk analyses of disease transmission; (c) The risk of transmission via blood and blood products; (d) Alternatives to the use of bovine-derived products in drug manufacture and other biologic industries; (e) Antemortem diagnosis of BSE and nv-CJD and the detection and inactivation of the disease agent in blood supplies. | human utilization, and the treatment of blood products from potential Creutzfeld-Jakob disease (CJD) donors; (2) recommends the FDA and the United States Department of Agriculture (USDA) continue to aggressively enforce regulations in place to prevent the occurrence/transmission of bovine spongiform encephalopathy (BSE) in the United States; (3) recommends the FDA, USDA, and Department of Health and Human Services continue to evaluate scientific data on transmissible spongiform encephalopathies (TSEs) and incorporate this information into their guidance and regulations; (4) recommends increased surveillance of new CJD cases as they arise in order to monitor for the possible appearance of new variant Creutzfeldt-Jakob disease (nv-CJD) via: (a) Referral of all deaths due to suspected CJD to an appropriately qualified pathologist for autopsy, with the submission of autopsy reports of confirmed cases to the National Prion Disease Pathology Surveillance Center at Case Western Reserve University, which is collaborating with the CDC. (b) Reporting of the diagnosis of CJD on the death certificate in all cases and the strengthening of the current system enabling health authorities to obtain clinical or pathologic data on the CJD cases of greatest public health concern. (c) Prompt notification of any case of new variant Creutzfeldt-Jakob disease to both the appropriate state health department and the CDC; and (5) recommends that well-controlled research be performed in the following |

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| | | | areas: (a) Elucidation of the mechanism of disease of TSEs; (b) Elucidation of the infectivity, dose requirements, and clearance of the disease agent to provide more data for adequate risk analyses of disease transmission; (c) The risk of transmission via blood and blood products; (d) Alternatives to the use of bovine-derived products in drug manufacture and other biologic industries; (e) Antemortem diagnosis of BSE and nv-CJD and the detection and inactivation of the disease agent in blood supplies. |
| H-150.961 | Irradiation of Food | It is the policy of the AMA to: (1) affirm food irradiation as a safe and effective process that increases the safety of food when applied according to governing regulations; and (2) consider the value of food irradiation to be diminished unless it is incorporated into a comprehensive food safety program based on good manufacturing practices and proper food handling, processing, storage, and preparation techniques. | Retain, still relevant. |
| H-150.980 | Milk and Human Health | The AMA reaffirms its policy that all milk sold for human consumption should be required to be pasteurized. | Retain, still relevant. |
| H-170.964 | Substance Use Education in Schools | Our AMA supports scientifically-based substance use education in schools. | Retain, still relevant. |
| H-170.980 | Health Education | It is the policy of the AMA (1) to urge all state medical societies to urge their respective state departments of education to: implement model health education curricula, act as clearinghouses for data on curriculum development, work with local school districts to implement health education programs and to seek funding for these programs; and (2) that the health education programs contain provisions for educator training and development of local community health advisory committees. | Retain, as amended to update language.<br><br>~~It is the policy of~~ The AMA (1) ~~to~~ urges all state medical societies to ~~urge~~ advocate that their respective state departments of education ~~to:~~ implement model health education curricula, act as clearinghouses for data on curriculum development, work with local school districts to implement health education programs and to seek funding for these programs; and (2) that the health education programs contain provisions for educator training and development of local |

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| | | | community health advisory committees. |
| H-170.988 | Health Education Legislation | The AMA (1) reaffirms current policy which supports the establishment of a comprehensive health education program in the elementary and secondary schools; and (2) encourages state and specialty medical societies to consider the introduction of such model legislation in their state legislatures. | Retain, as amended to update language.<br><br>The AMA (1) ~~reaffirms current policy which~~ supports the establishment of a comprehensive health education program in ~~the~~ elementary and secondary schools; and (2) encourages state and specialty medical societies to consider the introduction of such model legislation in their state legislatures. |
| H-170.989 | Health Fairs | The AMA (1) urges that the emphasis of health fairs be primarily educational and informative; and (2) encourages the sponsors of health fairs and similar single-purpose screening programs to emphasize the importance of the establishment of a personal doctor-patient relationship. | Retain, still relevant. |
| H-175.997 | Chelation Therapy | The AMA believes that chelation therapy for atherosclerosis is an experimental process without proven efficacy. | Retain, still relevant. |
| H-225.966 | Medical Staff Role in the Development of Substance Abuse Policies and Procedures | 1. Our AMA establishes the primacy of medical staff authority in substance abuse policy and procedures covering any pre-employment, credentialing, or other phases of physician evaluation.<br>2. Policy of the AMA states that medical staff must be involved in the development of the institution's substance abuse policy, including: (a) selection of analytical methods to ensure scientific validity of the test results, (b) determination of measures to maintain confidentiality of the test results, (c) in for-cause post-incident/injury testing, definition of standards for determining whether cause exists and which incidents and/or injuries will result in testing, and (d) development of mechanisms to address the physical and mental health of medical staff members.<br>3. The AMA believes all drug and alcohol testing must be performed only with substantive and procedural due process safeguards in place. | Retain as amended to update language.<br><br>Medical Staff Role in the Development of Substance Misuse ~~Abuse~~ Policies and Procedures<br><br>1. Our AMA establishes the primacy of medical staff authority in substance misuse ~~abuse~~ policy and procedures covering any pre-employment, credentialing, or other phases of physician evaluation.<br>2. Policy of the AMA states that medical staff must be involved in the development of the institution's substance misuse ~~abuse~~ policy, including: (a) selection of analytical methods to ensure scientific validity of the test results, (b) determination of measures to maintain confidentiality of the test results, (c) in for-cause post- |

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| | | | incident/injury testing, definition of standards for determining whether cause exists and which incidents and/or injuries will result in testing, and (d) development of mechanisms to address the physical and mental health of medical staff members.<br>3. The AMA believes all drug and alcohol testing must be performed only with substantive and procedural due process safeguards in place. |
| H-235.969 | Responsibility for Infection Control | AMA policy states that: (1) the hospital medical staff should have a multidisciplinary committee to oversee the surveillance, prevention and control of infection; (2) the infection control committee should report to the hospital medical staff executive committee; and (3) the medical staff's role, responsibility and authority in the infection control activities should be included in the medical staff bylaws. | Retain, still relevant. |
| H-25.988 | Community-Based Falls Prevention Programs | Our American Medical Association will work with relevant organizations to support community-based falls prevention programs. | Retain, still relevant. |
| H-25.995 | Exercise Programs for the Elderly | The AMA recommends that physicians: (1) stress the importance of exercise for older patients and explain its physiological and psychological benefits; (2) obtain a complete medical history and perform a physical examination that includes exercise testing for quantification of cardiovascular and physical fitness as appropriate, prior to the specific exercise prescription; (3) provide appropriate follow-up of patients' exercise programs; and (4) encourage all patients to establish a lifetime commitment to an exercise program. | Retain, still relevant. |
| H-295.879 | Improving Sexual History Curriculum in the Medical School | Our AMA (1) encourages all medical schools to train medical students to be able to take a thorough and nonjudgmental sexual history in a manner that is sensitive to the personal attitudes and behaviors of patients in order to decrease anxiety and personal difficulty with sexual aspects of health care; and (2) supports public messaging that encourages patients to discuss concerns related to sexual health with their physician and reinforces its commitment to helping patients maintain sexual health and well-being. | Retain, still relevant. |
| H-30.939 | Increasing Taxes on Alcoholic Beverages | It is AMA policy that federal, state, and local tax rates on alcoholic beverages be based on the grams of ethanol present in the beverage, not on the fluid volume of beverages such as beer, wine, and distilled spirits. | Retain, still relevant. |
| H-30.950 | Alcoholism in the Elderly | It is the policy of the AMA to: (1) encourage medical educators to consider expanding instructional material on alcohol and aging at all levels of medical education, particularly in residency and/or postgraduate training; and (2) cooperate with other | Retain as amended to update language. |

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| | | groups, such as the American Association of Retired Persons and appropriate government agencies, in public education programs for the elderly concerning alcohol-related problems. | ~~Alcoholism~~ Alcohol Use Disorder in Older Adults ~~the Elderly~~<br><br>~~It is the policy of the~~ Our AMA ~~to~~: (1) encourages medical educators to ~~consider~~ expand~~ing~~ instructional material on alcohol and aging at all levels of medical education, particularly in residency and/or postgraduate training; and (2) cooperate with other groups, such as the American Association of Retired Persons and appropriate government agencies, in public education programs for ~~the elderly~~ older adults concerning alcohol-related problems. |
| H-365.991 | NIOSH Cohort Mortality Studies | The AMA believes that physicians should (1) strive conscientiously to become familiar with the medical fitness requirements, the environment and the hazards of the work done by those they serve, and with the health and safety aspects of the products and operations involved; (2) communicate information about health hazards in a timely and effective fashion to individuals or groups potentially affected, and make appropriate reports to the scientific community; and (3) communicate understandably to those they serve any significant observations about their health, recommending further study, counsel, or treatment when indicated. | Retain with change in title from "NIOSH Cohort Mortality Studies" to "Physicians and Occupational Health Hazards" to better reflect content of the policy. |
| H-373.993 | Medication Adherence | Our AMA supports third parties in researching the effectiveness of personalized medication cards and other tools, including electronic reminders, intended to promote safe medication use, improve medication adherence, and improve health outcomes. Reminders should also be available in a variety of languages. Special attention should be devoted to reaching low literacy target audiences. | Retain, still relevant. |
| H-420.986 | Maternal and Child Health Care | The AMA opposes any further decreases in funding levels for maternal and child health programs; encourages more efficient use of existing resources for maternal and child health programs; encourages the federal government to allocate additional resources for increased health planning and program evaluation within Maternal and Child Health Block Grants; and urges increased participation of physicians through advice and involvement in the implementation of block grants. | Retain, still relevant. |
| H-425.977 | Encouraging Vision Screenings for Schoolchildren | Our AMA: (1) encourages and supports outreach efforts to provide vision screenings for school-age children prior to primary school enrollment; (2) encourages the development of programs to improve | Retain, still relevant. |

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| | | school readiness by detecting undiagnosed vision problems; and (3) supports periodic pediatric eye screenings based on evidence-based guidelines with referral to an ophthalmologist for a comprehensive professional evaluation as appropriate. | |
| H-425.986 | Challenges in Preventive Medicine | It is the policy of the AMA that (1) physicians should become familiar with and increase their utilization of clinical preventive services protocols; (2) individual physicians as well as organized medicine at all levels should increase communication and cooperation with and support of public health agencies. Physician leadership in advocating for a strong public health infrastructure is particularly important; (3) physicians should promote and offer to serve on local and state advisory boards; and (4) in concert with other groups, physicians should study local community needs, define appropriate public health objectives, and work toward achieving public health goals for the community. | Retain, still relevant. |
| H-430.998 | Use of the Choke and Sleeper Hold in Prisons | The AMA (1) does not regard the choke and sleeper holds as casually applied and easily reversible tranquilizers, but as the use of deadly force with the potential to kill; and (2) advocates that with all incidents involving the application of choke and sleeper holds there should be timely medical surveillance of the inmate. | Retain as amended to update language.<br><br>Use of the Chokeholds and Carotid Restraints ~~Sleeper Hold~~ in ~~Prisons~~ in People who are Incarcerated<br><br>The AMA (1) does not regard ~~the~~ chokeholds and ~~sleeper holds~~ carotid restraints as casually applied and easily reversible tranquilizers, but as the use of deadly force with the potential to kill; and (2) advocates that with all incidents involving the application of chokeholds and ~~sleeper holds~~ carotid restraints there should be timely medical surveillance of the ~~inmate~~ individual on which they were used. |
| H-440.827 | Surveillance of Antibiotic Use and Resistance | Our AMA: (1) recognizes the importance of public health and veterinary health surveillance for antimicrobial resistance and antibiotic use; and (2) recommends that public health and veterinary health agencies be adequately funded, as outlined in the President's Council of Advisors on Science and Technology Report, to achieve the surveillance goals and objectives outlined in the National Action Plan for Combating Antibiotic Resistant Bacteria. | Retain as amended to update language.<br><br>Our AMA: (1) recognizes the importance of public health and veterinary health surveillance for antimicrobial resistance and antibiotic use; and (2) recommends that public health and veterinary health agencies be adequately funded~~, as outlined in the President's Council of Advisors on Science and~~ |

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| | | | ~~Technology Report,~~ to achieve the surveillance goals and objectives outlined in the National Action Plan for Combating Antibiotic Resistant Bacteria. |
| H-440.831 | Protecting Patients and the Public Through Physician, Health Care Worker, and Caregiver Immunization | 1. AMA policy is that, in the context of a highly transmissible disease that poses significant medical risk for vulnerable patients or colleagues or threatens the availability of the health care workforce, particularly a disease that has the potential to become epidemic or pandemic, including influenza, and for which there is an available, safe, and effective vaccine, physicians, health care workers (HCWs), and family caregivers who have direct patient care responsibilities or potential direct exposure have an obligation to accept immunization unless there is a recognized medical reason to not be immunized. In scenarios in which there is a documented medical contraindication to immunization of a physician or HCW, appropriate protective measures should be taken.<br>2. Our AMA (a) encourages hospitals, health care systems, and health care providers to provide immunizations to HCWs against influenza and other highly transmissible diseases, at no cost to the employee, both for their own protection and to reduce the risk of infectious disease transmission to others; and (b) encourages health care institutions to develop mechanisms to maximize the rate of influenza immunization for HCWs, including the option of making immunization a condition of employment. | Retain, still relevant. |
| H-440.833 | Labeling and Recommended Protection for Sunglasses | Our American Medical Association recognizes, based on current evidence, that sunglasses that protect against 100% of both UVA and UVB radiation are currently the safest choice for consumers and recommends that manufacturers clearly label all sunglasses with the percentage of UVA and UVB radiation blocked so that consumers know the extent to which the glasses protect against both types of UV radiation. | Retain, still relevant. |
| H-440.834 | Next Generation Infectious Diseases Diagnostics | 1. Our American Medical Association supports strong federal efforts to stimulate early research and development of emerging rapid ID (infectious disease) diagnostic technologies through increased funding for appropriate agencies.<br><br>2. Our AMA supports the reduction of regulatory barriers to allow for safe and effective emerging rapid diagnostic tests, particularly those that address unmet medical needs, to more rapidly reach laboratories for use in patient care.<br><br>3. Our AMA supports improving the clinical integration of new diagnostic technologies into patient | Retain, still relevant. |

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| | | care through outcomes research that demonstrates the impact of diagnostics on patient care and outcomes, educational programs and clinical practice guidelines for health care providers on the appropriate use of diagnostics, and integration of diagnostic tests results into electronic medical records.<br><br>4. Our AMA supports efforts to overcome reimbursement barriers to ensure coverage of the cost of emerging diagnostics. | |
| H-440.846 | Antibiotic Use in Food-Producing Animals | Our AMA supports: (1) federal efforts to ban antibiotic use in food-producing animals for growth promotion purposes, including through regulatory and legislative measures; (2) a strong federal requirement that antibiotic prescriptions for animals be overseen by a veterinarian knowledgeable of the place and intended use of these drugs, under a valid veterinarian-client-patient relationship (VCPR); and (3) efforts to expand FDA surveillance and data collection of antibiotic use in agriculture. | Retain, still relevant. |
| H-440.851 | Influenza Vaccine Availability and Distribution | Our AMA will: (1) continue efforts to communicate strongly to its partners involved in influenza vaccine production and distribution that physicians must receive influenza vaccines in a timely and equitable manner in order to help immunize all patients =6 months of age as recommended by the Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP); (2) urge manufacturers and distributors of influenza vaccine to provide a dedicated ordering system for small- and medium-size medical practices to pre-order vaccine up to an appropriate volume threshold; (3) support federal actions to allow physicians (MDs and DOs) to form purchasing alliances to allow for competitive purchasing of influenza vaccine comparable to large purchasers currently supplying pharmacy and grocery chain stores with influenza vaccine; (4) communicate current ACIP recommendations on the influenza vaccine to physicians and assist the CDC in disseminating its informational letters and bulletins to physicians and other providers of the influenza vaccine when they become available in order to ensure compliance with the ACIP recommendations with respect to immunization of patients with influenza vaccine; (5) work with the CDC and other immunization partners to explore options to provide for timely influenza immunization of indigent or underserved populations, including exploring options to provide for the timely redistribution of state and federally funded influenza vaccines to facilities or groups within the state willing to appropriately manage, distribute, and administer the vaccine to indigent or underserved populations; (6) continue its collaboration with the CDC and other stakeholders in influenza vaccination to work to achieve the influenza immunization goals of Healthy | Retain as amended.<br><br>Our AMA will: (1) continue efforts to communicate strongly to its partners involved in influenza vaccine production and distribution that physicians must receive influenza vaccines in a timely and equitable manner in order to help immunize all patients =6 months of age and older as recommended by the Center for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices (ACIP); (2) urge manufacturers and distributors of influenza vaccine to provide a dedicated ordering system for small- and medium-size medical practices to pre-order vaccine up to an appropriate volume threshold; (3) support federal actions to allow physicians (MDs and DOs) to form purchasing alliances to allow for competitive purchasing of influenza vaccine comparable to large purchasers currently supplying pharmacy and grocery chain stores with influenza vaccine; (4) communicate current ACIP recommendations on the |

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| | | People 2020, with particular attention to improving demand for vaccine and achieving stability in the vaccine supply; (7) work with local public health officers through the Federation to respond to community flu vaccine shortages and possible influenza outbreaks to protect the public health; and, (8) urge the federal government to support, as a national priority, the development of safe and effective influenza vaccines employing new technologies and to continue to support adequate distribution to ensure that there will be an affordable, available and safe supply of influenza vaccine on an annual basis. | influenza vaccine to physicians and assist the CDC in disseminating its informational letters and bulletins to physicians and other providers of the influenza vaccine when they become available in order to ensure compliance with the ACIP recommendations with respect to immunization of patients with influenza vaccine; (5) work with the CDC and other immunization partners to explore options to provide for timely influenza immunization of those unable to pay ~~indigent~~ or underserved populations, including exploring options to provide for the timely redistribution of state and federally funded influenza vaccines to facilities or groups within the state willing to appropriately manage, distribute, and administer the vaccine to those unable to pay ~~indigent~~ or underserved populations; (6) continue its collaboration with the CDC and other stakeholders in influenza vaccination to work ~~to achieve the influenza immunization goals of Healthy People 2020, with particular attention to~~ on improving demand for vaccine and achieving stability in the vaccine supply; (7) work with local public health officers through the Federation to respond to community flu vaccine shortages and possible influenza outbreaks to protect the public health; and, (8) urge the federal government to support, as a national priority, the development of safe and effective influenza vaccines employing new technologies and to continue to support adequate distribution to ensure that there will be an affordable, available and safe supply of influenza vaccine on an annual basis. |

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| H-440.856 | Hospital Dress Codes for the Reduction of Health Care-Associated Infection Transmission of Disease | Our AMA encourages: (1) research in textile transmission of health care-associated infections (HAI); (2) testing and validation of research results before advocating for adoption of dress code policies that may not achieve reduction of HAIs; (3) all clinicians to assume "antimicrobial stewardship," i.e., adherence to evidence-based solutions and best practices to reduce of HAIs and HAI infection rates; and (4) all clinicians when seeing patients to wear attire that is clean, unsoiled, and appropriate to the setting of care. | Retain, still relevant. |
| H-440.881 | Liability Protection for Adult Vaccines | Our American Medical Association supports the expansion of the Vaccine Injury Compensation Fund to include any vaccine encouraged or recommended by the Advisory Committee on Immunization Practices for routine use in the adult population. | Retain as amended to update language.<br><br>Our American Medical Association supports the expansion of the Vaccine Injury Compensation Program ~~Fund~~ to include any vaccine ~~encouraged or~~ recommended by the Advisory Committee on Immunization Practices for routine use in the adult population. |
| H-440.908 | Nosocomial Transmission of Disease via Stethoscope | The AMA advocates that health care providers frequently clean their stethoscopes and take all reasonable precautions with their other hand-held instruments in order to minimize the potential risk of nosocomial infection. | Retain, still relevant. |
| H-440.918 | Improving Public Awareness of Immunization Guidelines | The AMA encourages and supports the frequent and regular dissemination of the Recommended Childhood Immunization Schedule recommendations through appropriate media throughout the US. | Retain, still relevant. |
| H-440.925 | Possible Repeal of the National Vaccine Injury Compensation Program | Our American Medical Association continues to support in principle the National Vaccine Injury Compensation Program. | Retain, still relevant. |
| H-440.939 | Qualifications for State Health Directors | The AMA recommends to state medical societies that they advocate with their respective legislatures the adoption of statutory requirements that the qualifications for State Health Director include a doctoral degree in medicine or osteopathy, public health training or experience, and preparation, both academic and experiential, adequate for the management of a large and complex health agency. | Retain, still relevant. |
| H-440.941 | High Cost and Shortage of Vaccines | The AMA seeks to ensure in an administratively efficient manner the ready availability of vaccines to immunize individuals at reasonable cost. | Retain, still relevant. |
| H-440.977 | Hepatitis B Vaccine | The AMA urges the appropriate use of hepatitis B vaccine and the dissemination of professional educational materials to increase the use of the hepatitis B vaccine by physicians whose patients are in high risk groups, including physicians in training and other medical personnel who come into contact | Retain, still relevant. |

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| | | with blood and blood products, tissues, secretions and excretions demonstrated to be potential reservoirs of hepatitis B virus. | |
| H-440.982 | Centers for Disease Control Funding | The AMA supports funding for the Centers for Disease Control that is adequate to support its important and expanding public health activities. | Retain, still relevant. |
| H-440.991 | Immunization Programs for Children | Our AMA (1) continues to support efforts toward the prevention of childhood disease through immunizations; (2) favors using its position in international health organizations to promote appropriate immunization programs for children throughout the world, especially in such critical and cost-effective areas as the prevention of poliomyelitis and measles; and (3) expresses the need for private and public research institutions to help develop more technically advanced products, such as new heat stable vaccines, necessary for the effective immunization of children throughout the world. | Retain, still relevant. |
| H-440.994 | Sexually Transmitted Disease Prevention | Our AMA endorses the use of the condom as an effective method of prevention of sexually transmitted disease and urges state and county medical societies to endorse the display and sale of condoms of assured quality by the usual retail outlets for the prevention of sexually transmitted disease, and suggests that each package contain information about the hazards of sexually transmitted disease. | Retain as amended to remove unclear language.<br><br>Our AMA endorses the use of the condom as an effective method of prevention of sexually transmitted disease and urges state and county medical societies to endorse the display and sale of condoms of assured quality by ~~the usual~~ retail outlets for the prevention of sexually transmitted disease, and suggests that each package contain information about the hazards of sexually transmitted disease. |
| H-445.985 | Physician and Health Institution Publicity and Responsibility | Our American Medical Association encourages physicians when engaged in public discourse related to health and medical science to disclose whether stated positions are based on peer-reviewed evidence, standard of care, or personal opinion. | Retain, still relevant. |
| H-45.989 | Child Safety Restraint Use in Aircraft | Our AMA supports (1) the use of and education about appropriate restraint systems for all children on all commercial airline flights; and (2) working with the Federal Aviation Administration, International Air Transport Association and other appropriate aviation regulators to establish criteria for appropriate child restraint systems. | Retain, still relevant. |
| H-45.998 | Aircraft Shoulder Harness | The AMA supports the National Transportation Safety Board position that the FAA take action to require the installation of approved shoulder harnesses for all seat locations in general aviation aircraft. | Retain, still relevant. |
| H-450.945 | Science in Medicine and Quality of Care | It is a critical role of the AMA to preserve, protect and enhance the quality of medical care now and in the future by: (1) advancing the art and science of | Retain, still relevant. |

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| | in Health System Reform | medicine and the health of the public; (2) advocating for patients, physicians and the public; (3) enhancing the profile and priority within the AMA of science as the basis of medicine; and (4) bringing science advocacy to the forefront of health system reform. | |
| H-460.899 | The Value of Peer Review in the Scientific Process | Our AMA reaffirms our strong support for the value of peer review system in ensuring openness and fidelity in the scientific process. | Retain, still relevant. |
| H-460.900 | The Value of Independent Scientific Advice | Our AMA reaffirms our strong support for the value of independent scientific advice provided by federal advisory panels. | Retain, still relevant. |
| H-460.904 | The Next Transformative Project: In Support of the BRAIN Initiative | Our AMA: (1) supports the scientific and medical objectives of the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative of mapping the human brain to better understand normal and disease process; (2) encourages appropriate scientific, medical and governmental organizations to participate in and support advancement in understanding the human brain in conjunction with the BRAIN Initiative; and (3) supports the continued Congressional allocation of funds for the BRAIN Initiative, thus providing for research and innovation in technologies that will advance knowledge of neurologic function and disease. | Retain, still relevant. |
| H-460.912 | Principles for Conduct and Reporting of Clinical Trials | Our AMA: (1) endorses the Association of American Medical Colleges' "Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials"; (2) commends the AAMC, the Centers for Education and Research in Therapeutics and the BlueCross BlueShield Association for the development and dissemination of these principles; (3) supports the timely dissemination of clinical trial data for public accessibility as permitted by research design and/or regulatory protocol; (4) supports the promotion of improved data sharing and the reaffirmation and enforcement of deadlines for submitting results from clinical research studies; (5) encourages the expansion of clinical trial registrants to ClinicalTrials.gov; and (6) will sign the petition titled "All Trials Registered; All Results Reported" at Alltrials.net that supports the registration of all past, present and future clinical trials and the release of their summary reports. | Retain as amended, to remove items that have been accomplished.<br><br>Our AMA: (1) ~~endorses the Association of American Medical Colleges' "Principles for Protecting Integrity in the Conduct and Reporting of Clinical Trials"; (2) commends the AAMC, the Centers for Education and Research in Therapeutics and the BlueCross BlueShield Association for the development and dissemination of these principles; (3)~~ supports the timely dissemination of clinical trial data for public accessibility as permitted by research design and/or regulatory protocol; (~~4~~ 2) supports the promotion of improved data sharing and the reaffirmation and enforcement of deadlines for submitting results from clinical research studies; and (~~5~~3) encourages the expansion of clinical trial registrants to ClinicalTrials.gov~~; and (6)~~ |

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| | | | ~~will sign the petition titled "All Trials Registered; All Results Reported" at Alltrials.net that supports the registration of all past, present and future clinical trials and the release of their summary reports~~. |
| H-460.943 | Potential Impact of Health System Reform Legislative Reform Proposals on Biomedical Research and Clinical Investigation | The AMA, to encourage and support the continuing development of new advances in science and medicine and the development and implementation of meaningful quality assurance programs essential to improving the delivery of medical and health care in the United States, advocates:<br>(1) Strong support and funding for medical education programs at all levels to attract and stimulate gifted students and physicians to receive training and experience in, and to participate in, basic science or clinically-oriented research programs.<br>(2) Strong financial and policy support for all aspects of biomedical science and research, including: basic science research (investigator initiated grant-funded research) in a wide variety of fields; laboratory-based clinical studies (including surgical studies); clinical studies and therapy trials; clinical outcomes research; behavioral science research, including studies to assess implementation of health promotion and/or disease prevention activities; and technology transfer research, with an emphasis on diffusing information about, training personnel in, and encouraging appropriate use of new technologies.<br>(3) Adequate federal funding for biomedical science programs, including an appropriate balance of funding for basic, clinical, health service, and public health/prevention research.<br>(4) Support and funding for evaluation and implementation research, including drug and technology assessment, medical device review, and developing and setting standards for computerized medical records. | Retain, still relevant. |
| H-460.970 | Maintaining Progress in Biomedical Research | Our AMA supports continued leadership by the Association in maintaining progress in biomedical research. | Retain as amended to clarify language.<br><br>Our AMA supports continued leadership by ~~the~~ our Association in maintaining progress in biomedical research. |
| H-460.989 | Animals as Experimental Subjects | The AMA encourages medical school faculty who use animals in the education of students to continue instruction of students on the appropriate use and treatment of animals. | Retain, still relevant. |
| H-460.998 | Support of Biomedical Research | Our AMA endorses and supports the following ten principles considered essential if continuing support and recognition of biomedical research vital to the delivery of quality medical care is to be a national | Retain, still relevant. |

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| | | goal: (1) The support of biomedical research is the responsibility of both government and private resources.<br><br>(2) The National Institutes of Health must be budgeted so that they can exert effective administrative and scientific leadership in the biomedical research enterprise.<br><br>(3) An appropriate balance must be struck between support of project grants and of contracts.<br><br>(4) Federal appropriations to promote research in specifically designated disease categories should be limited and made cautiously.<br><br>(5) Funds should be specifically appropriated to train personnel in biomedical research.<br><br>(6) Grants should be awarded under the peer review system.<br><br>(7) The roles of the private sector and of government in supporting biomedical research are complementary.<br><br>(8) Although the AMA supports the principle of committed federal support of biomedical research, the Association will not necessarily endorse all specific legislative and regulatory action that affects biomedical research.<br><br>(9) To implement the objectives of section 8, the Board will establish mechanisms for continuing study, review and evaluation of all aspects of federal support of biomedical research.<br><br>(10) Our AMA will accept responsibility for informing the public on the relevance of basic and clinical research to the delivery of quality medical care. | |
| H-470.953 | Evaluating Green Space Initiatives | Our AMA supports appropriate stakeholders in conducting studies to evaluate different green space initiatives that could be implemented in communities to improve patients' health and eliminate health disparities. | Retain, still relevant. |
| H-470.955 | Support of Protective Headgear (Helmets) in the Sport of Girls'/Women's Lacrosse | Our American Medical Association supports requiring approved protective headgear for all athletes participating in the sport of girls'/women's lacrosse. | Retain, still relevant. |
| H-470.956 | Injuries in Cheerleading | Our AMA: (1) supports the designation of cheerleading as a sport; and (2) recognizes the potential dangers of cheerleading, including the potential for concussion and catastrophic injury, and | Retain, with editorial amendments. |

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| | | supports the implementation of recommendations designed to improve its safety equivalent to those that apply to other athletic activities formally recognized as 'sports' by appropriate accrediting bodies. These include proper training of coaches, avoidance of inappropriate surfaces when performing stunts and adherence to rules for the proper execution of stunts. | Our AMA: (1) supports the designation of cheerleading as a sport; ~~and~~ (2) recognizes the potential dangers of cheerleading, including the potential for concussion and catastrophic injury~~,~~; and (3) supports the implementation of recommendations designed to improve its safety equivalent to those that apply to other athletic activities formally recognized as 'sports' by appropriate accrediting bodies. These include proper training of coaches, avoidance of inappropriate surfaces when performing stunts, and adherence to rules for the proper execution of stunts. |
| H-470.958 | Head Injury Prevention in Hockey | Our AMA will encourage that all levels of hockey effectively prevent head hits and dangerous checking. | Retain, still relevant. |
| H-470.960 | Soccer Injuries | Our AMA recognizes the problem of injuries in soccer and encourages additional studies into the incidence of soccer-related injuries and methods to reduce those injuries. | Retain, still relevant. |
| H-470.967 | Safety in Youth Baseball and Softball | The AMA urges youth baseball and softball organizations to adopt policies for the use of protective equipment and encourages sponsors of organized youth sports activities to adopt written emergency and first responder plans. | Retain, still relevant. |
| 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:<br><br>(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.<br><br>(2) Only licensed MDs, DOs, and licensed physician extenders practicing under the supervision of licensed MDs and DOs perform preparticipation examinations.<br><br>(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.<br><br>(4) The decision of when an injured athlete resumes participation is made by a qualified physician. | Retain, still relevant. |

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| | | (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. | |
| H-470.974 | Athletic Helmets | 1. Our AMA urges the Consumer Product Safety Commission and other appropriate agencies and organizations to establish standards to ensure that athletic and recreational equipment produced or sold in the United States provide protection against head and facial injury.<br><br>2. Our AMA: (a) supports requiring the use of head and facial protection by children and adolescents while engaged in potentially dangerous athletic and recreational activities; (b) encourages the use of head and facial protection for adults while engaged in potentially dangerous athletic and recreational activities; (c) encourages physicians to educate their patients about the importance of head and facial protection while engaged in potentially dangerous athletic and recreational activities; and (d) encourages the availability of rental helmets at all commercial settings where potentially dangerous athletic and recreational activities take place. | Retain, still relevant. |
| H-470.979 | Drugs and Athletes | The AMA favors cooperative efforts with the National Collegiate Athletic Association, the National Intercollegiate Athletic Association, the National Federation of High Schools and all other appropriate organizations to establish drug education, testing and treatment programs in all their respective athletic programs. | Rescind, as mostly accomplished and partly superseded by new data.<br><br>At the college level, in 2024 the NCAA Sports Science Institute revised their "Substance Misuse Prevention and Intervention: An Athletics Tool Kit." The NCAA Sport Science Institute on behalf of the Committee on Competitive Safeguards and Medical Aspects of Sports issues yearly updates that include prevention, education, treatment, and recovery components.<br><br>At the adolescent level, the American Society of Addiction Medicine issued guidelines on "Appropriate Use of Drug Testing in Clinical Addiction Medicine". This document includes recommendations about what level of risk justifies testing; |

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| | | | consent and other procedural safeguards; and appropriate use of test data.<br><br>At the high school level, the National Federation of State High School Associations (NFHS), published a 2024 opinion, "Revisiting Drug Testing in High Schools – Where Do We Stand" with a nuanced discussion of the "pros and cons" of drug testing in high school athletics and other optional activities.<br><br>Because relevant organizations have recently published material that covers in detail all areas included in H-470.979, your Council on Science and Public Health recommends that H-470.979 be rescinded. |
| H-470.994 | Non-Therapeutic Use of Pharmacological Agents by Athletes | Our AMA: (1) opposes the use of drugs for the purpose of enhancing athletic performance or sustaining athletic achievement. This action in no way should be construed as limiting a physician's proper use of drugs in indicated treatment of athletic injuries or clinical symptoms of individual athletes; and (2) endorses efforts by state level high school athletic associations to establish programs which include enforceable guidelines concerning weight and body fat changes on a precompetition basis for those sports in which weight management is a concern. | Retain, still relevant. |
| H-470.995 | Athletic (Sports) Medicine | Our AMA believes that:<br><br>(1) the Board of Education and the Department of Health of the individual states should encourage that an adequate Athletic Medicine Unit be established in every school that mounts a sports program;<br><br>(2) the Athletic Medicine Unit should be composed of an allopathic or osteopathic physician director with unlimited license to practice medicine, an athletic health coordinator (preferably a NATABOC certified athletic trainer), and other necessary personnel;<br><br>(3) the duties of the Athletic Medicine Unit should be prevention of injury, the provision of medical care with the cooperation of the family's physician and others of the health care team of the community, and the rehabilitation of the injured; | Retain, still relevant. |

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| | | (4) except in extreme emergencies, the selection of the treating physician is the choice of the parent or guardian and any directed referral therefore requires their consent;<br><br>(5) the Athletic Medicine Units should be required to submit complete reports of all injuries to a designated authority;<br><br>(6) medical schools, colleges, and universities should be urged to cooperate in establishing education programs for athletic health coordinators (NATABOC certified athletic trainers) as well as continuing medical education and graduate programs in Sports Medicine;<br><br>(7) high school administrators, athletic directors, and coaches to work with local physicians, medical societies, and medical specialty societies, as well as government officials and community groups to undertake appropriate measures to ensure funding to provide the services of a certified athletic trainer to all high school athletes; and<br><br>(8) not all high schools have the resources to procure the services of a certified athletic trainer and further recognizing that athletic trainers cannot be present at all practices and competitions, that the AMA encourage high school administrators and athletic directors to ensure that all coaches are appropriately trained in emergency first aid and basic life support. | |
| H-480.955 | "Keepsake" Fetal Ultrasonography | Our AMA: (1) supports the current Food and Drug Administration (FDA) policy on use of non-diagnostic fetal ultrasound, which views "keepsake" fetal videos as an unapproved use of a medical device; and (2) will lobby the federal government to enforce the current FDA position, which views "keepsake" fetal videos as an unapproved use of a medical device, on non-medical use of ultrasonic fetal imaging. | Retain, still relevant. |
| H-495.978 | Proper FDA Authority to Regulate Tobacco | Our AMA will continue to support federal legislation that would give the Food and Drug Administration strong regulatory authority over tobacco products. | Retain, still relevant. |
| H-495.987 | Taxation of All Tobacco Products and Electronic Nicotine Delivery Systems (ENDS) | 1. Our AMA will work for and encourages all levels of the Federation and other interested groups to support efforts, including education and legislation, to increase federal, state, and local excise taxes on all tobacco products and electronic nicotine delivery systems (ENDS), including e-cigarettes, in order to discourage use.<br><br>2. An increase in federal, state, and local excise taxes for such products should include provisions to make substantial funds available that would be allocated to health care needs and health education, and for the treatment of those who have already been afflicted by | Retain as amended to update language.<br><br>1. Our AMA ~~will work for and~~ encourages all levels of the Federation and other interested groups to support efforts, including education and legislation, to increase federal, state, and local excise taxes on all tobacco products and electronic nicotine delivery systems (ENDS), including e- |

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| | | tobacco-caused illness, including nicotine dependence, and to support counter-advertising efforts.<br><br>3. Our AMA continues to support legislation to reduce or eliminate the tax deduction presently allowed for the advertisement and promotion of all tobacco products; and advocates that the added tax revenues obtained as a result of reducing or eliminating such advertising/promotion tax deduction be utilized by the federal government for expansion of health care services, health promotion and health education. | cigarettes, in order to discourage use.<br><br>2. Our AMA supports ~~A~~an increase in federal, state, and local excise taxes for ~~such~~ tobacco products and electronic nicotine delivery systems (ENDS) ~~should~~ that includes provisions to ~~make substantial funds available that would be~~ allocate~~d~~ substantial funds for ~~to~~ health care needs and health education, ~~and for~~ the treatment of those who have already been afflicted by tobacco-caused illness, including nicotine dependence, and to support counter-advertising efforts.<br><br>3. Our AMA continues to support legislation to reduce or eliminate the tax deduction presently allowed for the advertisement and promotion of all tobacco products; and advocates that the added tax revenues obtained as a result of reducing or eliminating such advertising/promotion tax deduction be utilized by the federal government for expansion of health care services, health promotion and health education. |
| H-505.964 | International Tobacco Control Efforts | Our AMA:<br><br>(1) supports the international tobacco control efforts of the World Health Organization and urges the appropriate bodies and persons within the U.S. government (including Congress, the State Department, the Department of Commerce, and the Department of Health and Human Services) to participate fully in international tobacco control efforts, including supporting efforts to bring to fruition a Framework Convention on Tobacco Control;<br><br>(2) will work for the enactment of federal legislation or regulations that would prohibit the exportation of tobacco products to other countries. Pending the enactment of such legislation or regulation, our AMA (a) urges the U.S. government to alter trade policies and practices that currently serve to promote the | Retain, still relevant. |

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| | | world smoking epidemic; (b) continues to support the following activities: (i) federal legislation requiring health warning labels in the appropriate native language or symbolic form to be on packages of cigarettes exported and require foreign advertising by U.S. tobacco producers to be at least as restrictive as types of advertising permitted in the U.S.; (ii) labeling on tobacco products manufactured abroad to be at least as restrictive as those produced in the U.S.; (iii) opposition to efforts by the U.S. government to persuade countries to relax regulations concerning tobacco promotion and consumption; and (iv) encouragement of the World Health Organization to increase its worldwide anti-smoking efforts; (c) supports working with the World Medical Association as well as directly with national medical societies to expand activities by the medical profession to reduce tobacco use worldwide; (d) supports establishing close working relations with the World Health Organization to promote more physician involvement in anti-tobacco activities, particularly in developing and recently developed countries; (e) supports working with the Centers for Disease Control and Prevention's Office on Smoking and Health to promote worldwide anti-tobacco activities; (f) supports periodically monitoring the success of worldwide anti-tobacco efforts to control the growing worldwide smoking epidemic; and (g) supports the right of local jurisdictions to enact tobacco regulations that are stricter than those that exist in state statutes and encourages state and local medical societies to evaluate and support local efforts to enact useful regulations; and<br><br>(3) opposes any efforts by the government or its agencies to actively encourage, persuade or compel any country to import tobacco products and favors legislation that would prevent the government from actively supporting, promoting or assisting such activities. | |
| H-515.963 | Diagnosis and Management of Family Violence | Our American Medical Association recommends that questions to assess risk for family violence should be included within the context of taking a routine social history, past medical history, history of present illness, and review of systems as part of emergency, diagnostic, preventive, and chronic care management. | Retain as amended to update language.<br><br>Our American Medical Association recommends that questions to assess risk for family and intimate partner violence should be included within the context of taking a routine social history, past medical history, history of present illness, and review of systems as part of emergency, diagnostic, preventive, and chronic care management. |

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| H-515.973 | Memories of Childhood Abuse | The AMA: (1) recognizes that few cases in which adults make accusations of childhood sexual abuse based on recovered memories can be proved or disproved and it is not yet known how to distinguish true memories from imagined events in these cases; (2) encourages physicians to address the therapeutic needs of patients who report memories of childhood sexual abuse and that these needs exist quite apart from the truth or falsity of any claims; and (3) encourages physicians treating possible adult victims of childhood abuse to subscribe to the *Principles of Medical Ethics* when treating their patients and that psychiatrists pay particular attention to the *Principles of Medical Ethics with Annotations Especially Applicable to Psychiatry*. | Retain, still relevant. |
| H-515.995 | Corporal Punishment in Schools | The AMA (1) supports the abolition of corporal punishment in schools; (2) encourages universities that train teachers to emphasize alternative forms of discipline during their training; (3) encourages physicians to work toward the abolition of corporal punishment in their communities; and (4) encourages state medical societies to support legislation prohibiting corporal punishment in their state. | Retain, still relevant. |
| H-60.920 | Child Resistant Caps on Energy Drinks | Our American Medical Association urges that the US Food and Drug Administration and/or US Congress take legislative or regulatory action on the federal level to require child-resistant packaging on all high energy drinks manufactured in the United States. | Retain, still relevant. |
| H-60.983 | Statement of Concern Regarding Destructive Themes Contained in Music | (1) The AMA is concerned about the possible impact of destructive themes depicted in certain types of popular music. The vivid depiction of drug and alcohol use, suicide, violence, demonology, sexual exploitation, racism and bigotry could be harmful to some young people, especially vulnerable children and adolescents who are socially alienated from traditional value systems and positive support groups. (2) The AMA urges four activities: (a) parents should be aware of the themes depicted in music; monitor the concerts their children attend, the music videos they watch, and the albums they purchase and discuss the potential harmful effects of music themes with their children; (b) physicians should know about potentially destructive themes in some forms of music, and should work to increase awareness of patients and communities about these themes; (c) members of the entertainment industry, including sponsors of concerts, agents, and entertainers, should exercise greater responsibility in presenting music to young people; and (d) all music industry companies should voluntarily label albums in compliance with recently agreed upon labeling standards. | Retain, still relevant. |
| H-60.994 | Herpes Simplex and School Children | The AMA reaffirms the rights of children with herpes infections to a quality education, condemns exclusion of such children from regular classes with other children, and encourages state legislation which | Retain, still relevant. |

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| | | would mandate that children with herpes not be excluded from regular classes. | |
| H-95.979 | Curtailing Prescription Drug Abuse While Preserving Therapeutic Use - Recommendations for Drug Control Policy | Our AMA (1) opposes expansion of multiple-copy prescription programs to additional states or classes of drugs because of their documented ineffectiveness in reducing prescription drug abuse, and their adverse effect on the availability of prescription medications for therapeutic use; (2) supports continued efforts to address the problems of prescription drug diversion and abuse through physician education, research activities, and efforts to assist state medical societies in developing proactive programs; and (3) encourages further research into development of reliable outcome indicators for assessing the effectiveness of measures proposed to reduce prescription drug abuse. | Retain, as amended to update language.<br><br>Curtailing Prescription Drug Misuse ~~Abuse~~ While Preserving Therapeutic Use - Recommendations for Drug Control Policy<br><br>Our AMA (1) opposes expansion of multiple-copy prescription programs to additional states or classes of drugs because of their documented ineffectiveness in reducing prescription drug misuse ~~abuse~~, and their adverse effect on the availability of prescription medications for therapeutic use; (2) supports continued efforts to address the problems of prescription drug diversion and misuse ~~abuse~~ through physician education, research activities, and efforts to assist state medical societies in developing proactive programs; and (3) encourages further research into development of reliable outcome indicators for assessing the effectiveness of measures proposed to reduce prescription drug misuse ~~abuse~~. |
| H-95.987 | Using Controlled Substance Names in Commercial Products | The AMA opposes the advertising practice of naming products for controlled substances, implying that their use is exciting and desirable. | Retain, still relevant. |

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 5-A-25

Subject: Screening for Image Manipulation in Research Publications

Presented by: John T. Carlo, MD, MS, Chair

Referred to: Reference Committee E

## INTRODUCTION

Resolution 506-A-24, Screening for Image Manipulation in Research Publications," introduced by the Medical Student Section was referred. It stated that "our American Medical Association support the creation of a nationally collaborative database of manipulated images from retracted publications to provide a test bank for researchers developing augmented intelligence-integrated image screening tools." While there was only limited testimony on this item, concerns around the feasibility and scope of the request resulted in its referral for further study. This report serves as the Council on Science and Public Health's response to that referral.

## METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "image manipulation" and "AI image manipulation screening" and "generative adversarial networks." Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

## BACKGROUND

In a time of rampant misinformation and disinformation around medical science, the integrity of academic journals is of the utmost importance and allegations of research misconduct should be taken very seriously. As artificial intelligence (AI) tools become more advanced and integrated into the toolkits of researchers, the potential role of AI in research fraud should also receive more scrutiny.

While retractions may be done for a variety of reasons that may not necessarily be caused by research misconduct, many publishers are alarmed by the increasing rate of fraudulent images resulting in retractions.[1,2] Per the publishing watchdog RetractionWatch, the retraction rate in 2014 was 3.5 retracted articles per 10,000 published articles and rose to 11.2 retractions per 10,000 in 2022, with over 10,000 papers being retracted in 2023.[3] Interestingly, the incidences of retractions are relatively centralized, with researchers in Saudi Arabia (30.6 retractions per 10,000 articles), Pakistan (28.1 per 10,000), Russia (24.9 per 10,000), and China (23.5 per 10,000) having more retractions than the global rate.[4] As a result, some countries, such as China, have initiated national audits of research integrity.[5] It should be noted, however, that these statistics reflect retractions for any cause, not just image manipulation.

Generally, researchers with retractions will only have one retraction in their career, however there are a small-subset of serial offenders with more than ten retractions.[4] For publishers, the inverse appears to be true; in 2022, 51 percent of all retracted articles were published in the same 34 journals, sparking concerns of "paper mills," in which a publisher intentionally maintains low standards to increase publishing fees revenue, or malicious researchers have identified a deficiency in a publisher's review process and specifically target them for fraudulent articles.[3]

Beyond instances of malicious fraud, AI-generated images can also produce misleading or incorrect images in publications even if well-intended. For example, researchers have probed anatomical illustrations created by AI programs and found deficiencies in both their accuracy and level of detail.[6]

*The Role of AI*

AI can be a powerful tool for helping researchers communicate their message to a broader audience. For example, AI can help generate graphical abstracts, summarize data sets, or make images more readable.[7] As such, many journals maintain policies where authors must disclose where and when they used AI tools for the editors to adjudicate its appropriateness.[8-10]

While these tools are promising, advancements in AI, such as generative adversarial networks (GANs), pose a unique threat to image manipulation detection. GANs were introduced in 2014 and excel in generating highly realistic images known as "deepfakes" (a portmanteau of 'deep learning' and 'fake'). For example, researchers have found that even trained experts only correctly identify whether a Western blot image was real or AI-generated at a 50 percent rate, no better than a random guess.[11] A sample image has been provided in Appendix 1. Even prior to the introduction of GANs, the Department of Health and Human Service (HHS) Office of Research Integrity reported that 67 percent of their closed research misconduct cases between 2011 and 2015 were a result of manipulated images.[12] It is expected that as artificial image generation technology grows more sophisticated and more accessible, its use in research misconduct will similarly increase.

Given that these fraudulent images are not duplicated from existing images in the public domain, modern image integrity detection software may struggle at detecting deepfakes. GANs, and other AI tools, have been used to generate false images or video for a variety of applications beyond research misconduct, including financial fraud, sowing political discontent, and even pornography.[13,14] The programs used to make these images are generally accessible and usable on desktop computers and do not require any specialized equipment.[15]

## CURRENT APPROACHES

The original resolution requested a "nationally collaborative database of manipulated images from retracted publications" for researchers developing tools to combat research misconduct. It should be noted that resources which may satisfy these requirements currently exist. For example, the HHS, Office of Research Integrity maintains publicly available resources on image forensics, academic publishers regularly share open-source databases, and non-profit entities such as RetractionWatch maintain searchable databases of retracted publications.[16-18] While these resources may not fully accomplish the goals of the original resolution, they do point to the generally available nature of manipulated images from retracted articles.

Additionally, nearly all major journal publishers currently utilize detection software, suggesting that there are currently market forces to push these kinds of research and development efforts. While the use of AI technologies to conduct research fraud is new, the concept of manipulating

images is not. As such, academic journals have generally been quick to adopt new technologies to keep up with the advances of malicious actors. For example, the AI image detection tool Proofig is currently partnered with journals published by Elsevier, Springer Nature, Science, the American Association of Cancer Research, the Royal Society of Chemistry, the American Society of Clinical Investigation, the Company of Biologists, Mary Ann Liebert, Inc., Compuscript Ltd, Sage Publishing, and the Taylor and Francis publishing group.[19] Proofig claims that approximately 25 percent of all manuscripts screened have been found to have some level of image manipulation, which can then be manually screened by an editor. Other tools, such as ImageTwin or Imachek, are also used by journal publishers to identify image manipulation. Other publishers, such as the PLOS family of journals, additionally require authors to submit raw image files prior to publication to detect image manipulation in their submissions.[20]

Finally, given the widespread accessibility of software to generate falsified images, it is unclear what value a centralized repository of retracted images would be. Technologies such as Deep AI are fully open source, meaning they are broadly available to the public for free use, or other programs such as DALL-E 3 or IMAGEN can be licensed at rates as low as 3 cents per image.[21,22] Particularly if a database were of specifically images from retracted publications, those are more likely to be generated using outdated technology, given the rapid rate of innovation in this space, or they were already detectable, given they were flagged for retraction. Additionally, it is unclear whether journal publishers retain the ownership rights for images after retraction, which may present intellectual property challenges for such a database.

Experts in the field of research misconduct describe the current publishing landscape as an "arms race," wherein generative software and detection software are both rapidly evolving to keep up with the developments of their counterpart.[23] This situation is likely unsustainable, and simply creating more sophisticated detection tools will likely only result in more sophisticated generation tools, and vice versa. Rather, some experts have argued that research misconduct is a symptom of the high pressures placed on researchers by the academic ecosystem, particularly the "publish or perish" mindset coming from the emphasis employers and funders place on academic publishing, and lack of interest in reproducibility.[24]

## CURRENT AMA POLICY

Our AMA maintains robust policy on research misconduct, including through the Code of Medical Ethics. Full text of cited policies can be found in the appendix of this report.

Our AMA's opposition to research misconduct can be found in policy H-460.972, "Fraud and Misrepresentation in Science," which notes that "Our AMA supports the promotion, through AMA publications and other vehicles, of (a) A clear understanding of the scientific process, possible sources of error, and the difference between intentional and unintentional scientific misrepresentation. (b) Multidisciplinary discussions to formulate a standardized definition of scientific fraud and misrepresentation that elaborates on unacceptable behavior." This policy also notes that "Our AMA supports the development of specific standardized guidelines dealing with the disposition of primary research data, authorship responsibilities, supervision of research trainees, role of institutional standards, and potential sanctions for individuals proved guilty of scientific misconduct." Additionally, policy H-460.980, "Ethical and Societal Considerations in Research," states that "[e]ach institution should have a system both for monitoring the conduct of biomedical research and for investigating and reporting allegations of research misconduct."

Code of Medical Ethics, opinion 7.1.5, "Misconduct in Research," states "[b]iomedical and health research is intended to advance medical knowledge to benefit future patients. To achieve those

goals physicians who are involved in such research maintain the highest standards of professionalism and scientific integrity." Additional opinions, including 7.1.1, "Physician Involvement in Research," ("[…] physicians who are involved in research should […] [a]dhere to rigorous scientific and ethical standards in conducting, supervising, and disseminating results of the research"), and 7.2.1, "Principles for Disseminating Research Results," ("[…] physicians should […] [r]eport the results of research accurately, including subsequent negative findings. This is particularly important where the findings do not support the research hypothesis") further emphasize the importance of proper conduct by physicians performing research.

## CONCLUSION

Research misconduct undercuts trust and has a corrosive impact on the practice of medicine. While cases of fraud have happened infrequently in the past, rising rates of retractions have resulted in concerns that widespread access to AI tools which quickly generate text and images are causing fraud to become more commonplace. Our AMA's stance on research misconduct is clear, robust, and supports the use of a variety of means to reduce its prevalence. While it is possible that the creation of a repository of falsified images for researchers to use may improve AI detection tools, it is also clear that these efforts are already underway, being developed by commercial entities, and utilized by many, if not all major journal publishers.

## RECOMMENDATIONS

The Council on Science and Public Health recommends that the following be adopted in lieu of Resolution 506-A-24, and that the remainder of the report be filed:

1. AMA Policy H-460.972, "Fraud and Misrepresentation in Science," be amended by addition to read as follows:

    1. Our American Medical Association supports the promotion of structured discussions of ethics that include research, clinical practice, and basic human values within all medical school curricula and fellowship training programs;
    2. Our AMA supports the promotion, through AMA publications and other vehicles, of
        a. A clear understanding of the scientific process, possible sources of error, and the difference between intentional and unintentional scientific misrepresentation.
        b. Multidisciplinary discussions to formulate a standardized definition of scientific fraud and misrepresentation that elaborates on unacceptable behavior.

        Our AMA supports the promotion of discussions on the peer review process and the role of the physician investigator.
    3. Our AMA supports the development of specific standardized guidelines dealing with the disposition of primary research data, authorship responsibilities, supervision of research trainees, role of institutional standards, and potential sanctions for individuals proved guilty of scientific misconduct.
    4. Our AMA supports the sharing of information about scientific misconduct among institutions, funding agencies, professional societies, and biomedical research journals
    5. Our AMA will educate, at appropriate intervals, physicians and physicians-in-training about the currently defined difference between being an "author" and being a "contributor" as defined by the Uniform Requirements for Manuscripts of the International Committee of Medical Journal Editors, as well as the varied potential for industry bias between these terms.

6. Our AMA supports policies requiring authors to disclose the use of generative artificial/augmented intelligence programs to best allow for content to be reviewed for intentional and unintentional scientific misrepresentation.
7. Our AMA supports efforts to disseminate accurate and valid research findings, and to combat research and publication fraud, in the face of rapidly advancing technology. (Modify HOD Policy)

2. AMA Policy H-460.980, "Ethical and Societal Considerations in Research" be reaffirmed. (Reaffirm HOD Policy)

Fiscal Note: less than $1,000

## RELEVANT AMA POLICY

**AMA Publications G-630.090**

Our American Medical Association policy on its publications includes the following:

1. JAMA and other AMA scientific journals should display a disclaimer in prominent print that the editorial views are not necessarily AMA policy.
2. Our AMA, in all of its publications and correspondence, will use the correct title for the medical specialist.
3. Our AMA recommends that medical journal articles using acronyms should have a small glossary of acronyms and phrases displayed prominently in the article.
4. The House of Delegates affirms that JAMA and The JAMA Network journals shall continue to have full editorial independence as set forth in the AMA Editorial Governance Plan.

**Fraud and Misrepresentation in Science H-460.972**

8. Our American Medical Association supports the promotion of structured discussions of ethics that include research, clinical practice, and basic human values within all medical school curricula and fellowship training programs;
9. Our AMA supports the promotion, through AMA publications and other vehicles, of
    a. A clear understanding of the scientific process, possible sources of error, and the difference between intentional and unintentional scientific misrepresentation.
    b. Multidisciplinary discussions to formulate a standardized definition of scientific fraud and misrepresentation that elaborates on unacceptable behavior.
10. Our AMA supports the promotion of discussions on the peer review process and the role of the physician investigator.
11. Our AMA supports the development of specific standardized guidelines dealing with the disposition of primary research data, authorship responsibilities, supervision of research trainees, role of institutional standards, and potential sanctions for individuals proved guilty of scientific misconduct.
12. Our AMA supports the sharing of information about scientific misconduct among institutions, funding agencies, professional societies, and biomedical research journals
13. Our AMA will educate, at appropriate intervals, physicians and physicians-in-training about the currently defined difference between being an "author" and being a "contributor" as defined by the Uniform Requirements for Manuscripts of the International Committee of Medical Journal Editors, as well as the varied potential for industry bias between these terms.

**Ethical and Societal Considerations in Research H-460.980**

1. Private organizations and academic institutions should jointly develop a means to continue and enhance broadly based study and discussion of ethical and societal issues in biomedical research.
2. The federal government should provide the resources to support new initiatives within the National Institutes of Health for the funding of research studies in bioethics. Existing federal programs that fund bioethical research studies should be preserved. Private foundations should be encouraged to provide resources to support research studies in bioethics.
3. A uniform set of federal regulations governing research with human subjects, based on the core regulations of the Department of Health and Human Services should be adopted by all federal agencies. Uniformity should not preclude additions to Department regulations that do not conflict with the core regulations or that enhance the protection of research subjects.
4. Associations of regional institutional review boards (IRBs) should be formed to enhance IRB performance through the development of educational site visits and local workshops.

5. Each institution should have a system both for monitoring the conduct of biomedical research and for investigating and reporting allegations of research misconduct.
6. All investigators involved in research projects should be responsible for the clear articulation and enforcement of standards that ensure the integrity of scientific data and conclusions. Regardless of whether the research project is a result of individual or collaborative efforts, investigators should thoroughly understand the data and conclusions in research publications and studies.
7. As part of their formal training in research investigation, graduate, medical and postdoctoral students should be instructed on the importance of adhering to the ethical and scientific requirements in research conduct and in the reporting of research results.
8. Our American Medical Association encourages study of the inclusion of Socioeconomic Status (SES) data in clinical and public health research identify appropriate minimum standards for the inclusion of such data in research studies.
9. Our AMA:
    a. opposes policies requiring scientific disclosures of confidential medical records consistent with Policy H-315.983, "Patient Privacy and Confidentiality".
    b. supports the use of all credible scientific data in the development of public policy while safeguarding confidentiality of patient information.

**7.1.5 Misconduct in Research**

Biomedical and health research is intended to advance medical knowledge to benefit future patients. To achieve those goals physicians who are involved in such research maintain the highest standards of professionalism and scientific integrity.

Physicians with oversight responsibilities in biomedical or health research have a responsibility to ensure that allegations of scientific misconduct are addressed promptly and fairly. They should ensure that procedures to resolve such allegations:

(a) Do not damage science.

(b) Resolve charges expeditiously.

(c) Treat all parties fairly and justly. Review procedures should be sensitive to parties' reputations and vulnerabilities.

(d) Maintain the integrity of the process. Real or perceived conflicts of interest must be avoided.

(e) Maintain accurate and thorough documentation throughout the process.

(f) Maintain the highest degree of confidentiality.

(g) Take appropriate action to discharge responsibilities to all individuals involved, as well as to the public, research sponsors, the scientific literature, and the scientific community.

**7.1.1 Physician Involvement in Research**

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

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

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

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

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

(a) Participate only in those studies for which they have relevant expertise.

(b) Ensure that voluntary consent has been obtained from each participant or from the participant's legally authorized representative if the participant lacks the capacity to consent, in keeping with ethics guidance. This requires that:

(i) prospective participants receive the information they need to make well-considered decisions, including informing them about the nature of the research and potential harms involved;

(ii) physicians make all reasonable efforts to ensure that participants understand the research is not intended to benefit them individually;

(iii) physicians also make clear that the individual may refuse to participate or may withdraw from the protocol at any time.

(c) Assure themselves that the research protocol is scientifically sound and meets ethical guidelines for research with human participants. Informed consent can never be invoked to justify an unethical study design.

(d) Demonstrate the same care and concern for the well-being of research participants that they would for patients to whom they provide clinical care in a therapeutic relationship. Physician researchers should advocate for access to experimental interventions that have proven effectiveness for patients.

(e) Be mindful of conflicts of interest and assure themselves that appropriate safeguards are in place to protect the integrity of the research and the welfare of human participants.
(f) Adhere to rigorous scientific and ethical standards in conducting, supervising, and disseminating results of the research.

**7.2.1 Principles for Disseminating Research Results**

Physicians have an ethical responsibility to learn from and contribute to the total store of scientific knowledge. When they engage in biomedical or health research, physicians have obligations as scientists, which include disseminating research findings. Prompt presentation to scientific peers and publication of research findings are foundational to good medical care and promote enhanced patient care, early evaluation of clinical innovations, and rapid dissemination of improved techniques.

To fulfill their ethical responsibilities with respect to sharing research findings for the ultimate benefit of patients, physicians should:

(a) Advocate for timely and transparent dissemination of research data and findings. Physicians should not intentionally withhold information for reasons of personal gain.
(b) Report the results of research accurately, including subsequent negative findings. This is particularly important where the findings do not support the research hypothesis.
(c) Maintain a commitment to peer review.
(d) Disclose sponsorship and conflicts of interest relating to the research, in keeping with ethics guidance.
(e) Be responsible in their release of research results to the media, ensuring that any information the researcher provides is prompt and accurate and that informed consent to the release of information has been obtained from research participants (or participants' legally authorized representative when the participant lacks decision-making capacity) prior to releasing any identifiable information.

In rare circumstances, the potential for misuse of research results could affect the decision about when and whether to disseminate research findings. Physician-researchers should assess foreseeable ramifications of their research in an effort to balance the promise of benefit against potential harms from corrupt application. Only under rare circumstances should findings be withheld, and then only to the extent required to reasonably protect against misuse.

APPENDIX 1

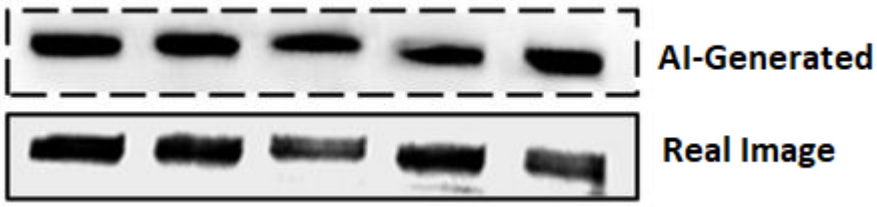


Figure 1. Sample of artificially generated (top) and real (bottom) Western blot images. When this specific image was provided to experts, only 4 of 23 participants were able to correctly identify the artificially generated image. For all images used in this study, experts had a 50 percent accuracy rate for detecting artificially generated images. Adapted from Qi et al.[11]

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REPORT 8 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (A-25)
Explainability of Artificial/Augmented Intelligence and Machine Learning Algorithms
(Reference Committee E)

## EXECUTIVE SUMMARY

BACKGROUND. In continuance of the American Medical Association's (AMA) interest in the oversight and regulation of augmented intelligence (AI) and machine learning (ML) algorithms in the medical system, the Council on Science and Public Health has initiated a report to examine the concept of explainability in the context of AI/ML algorithms.

Briefly, "explainable AI" (XAI) describes AI/ML-enabled algorithms whose decisions would be understandable to an expert in the field and can be evaluated for accuracy or other external factors. At its core, the implementation and use of XAI is a question of physician autonomy. In instances where algorithms can explain their decision-making, they are useful tools for scraping huge data sets and recognizing patterns that may have been imperceptible to the clinician. In those cases, those algorithms are augmenting the physician's skillset, and the outputs can be viewed as recommendations, which can be discarded if the physician's training and expertise disagree with the conclusion. However, if clinical AI algorithms are not explainable, the clinician's training and expertise is removed from decision-making, and they are presented with information they may feel compelled to act upon without knowing where it came from or being able to assess accuracy of the conclusion.

METHODS. English language articles were selected from searches of PubMed and Google Scholar using the search terms "AI explainability," "black box algorithm," and "white box algorithm." 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. Generally, humans have low trust of AI, particularly when it is involved in decision-making. One proposed approach for rectifying this lack of trust is through AI devices providing explanations for how it arrived at a conclusion. While XAI is highly appealing for building trust, it is less clear that it is implementable for medical applications. A common fallacy when evaluating AI/ML algorithms is to assume that they approach problems and datasets in the same way that a human would. Algorithms cannot feel, intuit, or infer, but rather perform a series of highly complex calculations. This report discusses several key concepts around explainability, including the motivations for its use, the technical feasibility, regulatory approaches used in both medical and non-medical fields, and recommendations for moving towards more trustworthy AI development.

CONCLUSION. Ironically, the concept of explainability is hard to explain. It is complex, nuanced, and asks profound questions on human cognition and the meaning of trust. The appeal of explainability is clear – particularly in medicine, where decisions can have life or death consequences. Being told a computer has decided you do not qualify for treatment would be disturbing for patients and their physicians. Physicians have trained for decades to utilize context and see the whole patient's clinical picture, and a binary "yes/no" output from a black box may feel restrictive and lacking nuance. Instead, medicine may wish to leverage its experience with other unexplainable phenomena, and push for explainability while requiring safety and efficacy.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 8-A-25

Subject: Explainability of Artificial/Augmented Intelligence and Machine Learning Algorithms

Presented by: John T. Carlo, MD, MS, Chair

Referred to: Reference Committee E

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## INTRODUCTION

In continuance of the American Medical Association's (AMA) interest in the oversight and regulation of augmented intelligence (AI) and machine learning (ML) algorithms in the medical system, the Council on Science and Public Health have has initiated this report to examine the concept of explainability. To keep the focus of this report narrow, it is the Council's intent to regularly examine issues relevant to AI/ML's intersection with science and public health and develop policy recommendations as necessary. This report will also serve as an opportunity to define key concepts related to AI in a field where groups are using different definitions of the same term, leading to confusion.

Briefly, "explainable AI" (XAI) describes algorithms whose decisions would be understandable to an expert in the field and can be evaluated for accuracy or other external factors. AI/ML tools in the medical setting can take a variety of forms, ranging from those which interpret images, make diagnostic recommendations, or have a conversation with a patient using a large-language model (LLM). All of these tools would theoretically be able to be developed using an XAI framework. An example of this includes an algorithm trained to distinguish between pictures of wolves and huskies to help track endangered species.[1] The program became very good at detecting wolves, but when researchers probed deeper, they discovered that their AI had instead learned to identify pictures of snow, which just so happened to be present in every picture of a wolf (see Appendix 1). Had the algorithm been required to present its explanation, any expert would have been able to discard the results as identifying snow. When translating this example to the medical ecosystem, some experts have questioned whether physicians and patients will ever fully be able to trust or implement AI decision-making tools in the clinic if the output is not explainable for fear of misdiagnosis or improper treatment plans.

## METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "AI explainability," "black box algorithm," and "white box algorithm." Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

## BACKGROUND

Prior to the 2000s, most augmented/artificial intelligence (AI) applications were a series of "if, then" statements in which an end user could conceivably recreate the program's logic, albeit in a

more time-intensive manner.[2] In 2000, researchers began to develop what was known as "machine learning" (ML), which was a much more complex network of equations that began to obscure the logic used to arrive at conclusions, even to the designers of ML programs.[3] While orders of magnitude more powerful than previous iterations of AI tools, the inability for many ML tools to describe their decision-making process has resulted in significant discussion as to the value of XAI.

At its core, the implementation and use of XAI places physician autonomy in question. In instances where algorithms can explain their decision-making, they may be useful tools for assessing huge data sets and recognizing patterns that are imperceptible to a clinician. In those cases, those algorithms are augmenting the physician's skillset by consolidating large volumes of data, with outputs which can support a physician's decision-making or be discarded if the physician's training and expertise disagree with the conclusion. However, if clinical AI/ML algorithms are not explainable, the clinician's training and expertise is removed from decision-making, and they are presented with information they may feel compelled to act upon without knowing where it came from or being able to assess quality and accuracy of the conclusion.

To help readers conceptualize the concepts of XAI, this report discusses several simplified, hypothetical scenarios. However, to best convey the utility of XAI, these hypotheticals will often describe instances where AI performed poorly or resulted in negative patient outcomes. This focus, however, should not be construed as a blanket criticism of AI in the clinic, but rather highlight opportunities where the physician voice can be used to push for development of safe, responsible, and impactful products for patients.

## TRUSTWORTHINESS OF OUTPUTS

Briefly, trustworthiness describes what a person (or in this case, an AI tool) has done to demonstrate that they can be trusted. Historically, AI developers have used accuracy or other performance measures as a proxy for trustworthiness, but experts have argued that this alone is insufficient.[4] Physicians and their patients may have many concerns about AI in medicine beyond accuracy, including privacy or fairness. One of the steps proposed by ethics researchers and regulatory bodies to demonstrate AI trustworthiness is through explainability.[5]

Take for example, a hypothetical AI/ML algorithm that provides recommendations on whether to prescribe antibiotics for patients with a bacterial infection. If that algorithm were not explainable, also known as a "black box" algorithm, then an output may be a simple 'do not treat' versus 'treat'. In this situation, the physician may feel pressured to defer to the AI/ML algorithm, as a specialized tool designed to determine the appropriateness of an antibiotic and accept the recommendation. If the patient were to ask why they were not getting treatment, the physician would have a challenging time communicating the reasoning due to the lack of explainability of the AI/ML algorithm, undercutting the physician's role as a trusted expert.

By contrast, if that algorithm were explainable, also known as a "white box" or "glass box" algorithm, then the same hypothetical output would provide more context and may read "When compared to 5000 patients of similar age, sex, weight, social history, body temperature, and presence of headache, the patient is 80 percent likely to have a mild viral infection and a five percent chance of having a severe bacterial infection. Given the risk for adverse side effects and antibiotic resistance, it is not recommended to initiate antibiotics." This explanation provides the physician with information about the size of population being compared, the demographics being compared, the inputs it considered, and the risks it balanced – but potentially contains several mistakes, inaccuracies, or extraneous information or misses important context to the patient case. When presented with this explanation, a physician could recognize that a culture is most useful to

differentiate between a viral and bacterial infection, or that locally there has been a significant prevalence of viral infections increasing the likelihood of a viral over bacterial infection where antibiotics may be warranted. In this instance, a physician could give this AI recommendation lower value in their differential diagnosis, but could still glean some useful insights, such as recognizing that in a similar patient population, their patient is generally perceived as low risk for severe infection.

Generally, humans have low trust of AI, particularly when it is involved in decision-making. In one study, even when participants were explicitly told that an automated decision-making tool was performing better than them, 81 percent of participants still chose to ignore the tool's inputs.[6] The researchers posit that this response may come from an innate feeling that humans use "perfected automation," meaning humans perform the same calculations as the AI/ML tool but without error. Thus, the majority of AI tool users will only ever incorporate an AI tool's output into their own decision making, rather than solely rely on it.[7] As such, explainability for AI/ML systems may assist to overcome this hesitance for use. Even when the stakes are far lower than someone's health, studies have found that people are more likely to accept an algorithm's movie recommendation if it comes with an explanation as to why (such as, it is similar to other movies you have watched), and even more when the reason for the recommendation is easily understandableand conveys high value information (it has your most frequently viewed actor in it).[8]

In the hypothetical example of an algorithm recommending against prescribing antibiotics, if the patient were to develop a severe bacterial infection, then the importance of explainability for trustworthiness is further amplified. If the algorithm were a black box algorithm and simply got the recommendation wrong, trust is fractured. Studies have found the human response to AI/ML algorithms is that a single failure from a black box algorithm causes a person to severely underestimate the algorithm's level of accuracy in the future, often fully disregarding recommendations in perpetuity.[6] However, with a white box algorithm, even though the logic may be flawed, the user can see the decision-making process, understand what its limitations are, and may still feel comfortable using it in the future, albeit with more caution.[9] This trend also matches the perceptions of patients; in studies where AI is a black box, or otherwise removes their physician's experience and training from their decision-making, patient trust decreases and concerns about liability increase.[10-12]

It is unclear how the use and recommendations for AI will be disclosed to patients or documented. Current AMA policy calls for "a risk- and impact-based approach that considers the unique circumstance of AI and its use case. The need for transparency and disclosure is greater where the performance of an AI-enabled technology has a greater risk of causing harm to a patient." In instances where AI tools are aiding in diagnosis but do not provide explanations (or the explanation is inadequate for non-experts), disclosure of an AI recommendation into a patient's medical record could have serious implications such as insurance reimbursement or on the patient-physician relationship, particularly in instances where the physician does not agree with the AI recommendation that their patient can view.

This tension further escalates as the conditions of interest become more serious. For example, in the mid-2010s, the electronic health record vendor Epic released a module for the detection of sepsis which utilized a proprietary, black box model. When external researchers probed the performance of the model, they found that while it did detect seven percent of true sepsis cases that clinicians missed, the software had a 67 percent false negative rate across all sepsis cases.[13] Further, the model had a high false-positive rate, generating electronic alerts on 18 percent of *all* hospitalized patients (compared to the true positive sepsis rate of seven percent), resulting in significant "alert fatigue" in clinicians. After working with the model for prolonged periods of

time, it is possible that clinicians would begin to ignore the alerts and instead rely on traditional clinical signs for sepsis diagnosis.

*Technical Feasibility*

While XAI is highly appealing for building trust in this new technology, it is less clear that it is implementable for medical applications. A common fallacy when evaluating AI/ML algorithms is to assume that it approaches problems and datasets in the same way a human would. While the field of human cognition is vast and complicated, two simple techniques that humans use to assess information and make decisions are linear logic and inference.[14] Briefly, humans often rely on linear logic (if A is true, then B is true) to understand information, then use intuition and experience to fill in (or infer) where there are information gaps. For example, if a 50-year old patient with a family history of colon cancer were to present with occult blood in their stool, a physician is likely to infer from a constellation of risk factors, signs and symptoms to assess that the patient is at high risk of having colon cancer. They would then use a confirmatory test, such as a colonoscopy with biopsy, to create a linear logic chain to confirm their diagnosis.

AI/ML algorithms do not process information in the same way humans do.[15] Thinking is a purely biologic process and cannot currently be replicated by any artificial technique. As such, AI/ML cannot infer. In a typical ML model, every single input is assigned a specific weight, and the output is a sum or other computation of those weights. Weights are based on datasets used to "train" the algorithm and are often dynamic and/or non-linear. These systems are generally referred to as "neural networks" to invoke the imagery of the hundred billion neurons and their interconnectivity similar to the human brain.[16] To help visualize the complexity of these connections, a neural network diagram for a simple AI/ML algorithm used to differentiate between 10 unique digits (0 through 9) from handwriting samples is included as Appendix 2.[17] Due to the complexity of the computations, even the developers of AI/ML algorithms may not fully comprehend how their programs arrived at an output when the process is too complex, and would thus argue that explainability is an unrealistic expectation humans have of AI/ML.[18]

*Building Bridges to Explainability*

While there may never be a way to truly convert the computation of an AI/ML algorithm into a comprehensible form for human interpretation, there are promising techniques being developed that do provide the user with *more* information to build confidence in AI, albeit incomplete. Some of these techniques include Locally-Interpretable Model-agnostic Explanation (LIME),[19] Gradient-weighted Class Activation Mapping (Grad-CAM),[20] and Occlusion Sensitivity (OS).[21]

Consider a hypothetical AI/ML algorithm that has been designed to detect lung tumors. In this example, the physician inputs a chest MRI for their patient, and the program returns a score for the likelihood a malignant tumor has been detected. In instances where the score is high, the obvious follow-up is: how can you tell? What factors is the algorithm using to distinguish between malignant and benign? In this hypothetical, the algorithm is only trained to calculate a "likelihood of tumor" value from millions of interconnected calculations and report "malignant" if the value is above a pre-determined value, or "benign" if the value is below.

To bridge the gap between the complex AI/ML algorithm and an explainable, interpretable result, a technique such as OS can be utilized. OS analysis highlights the area of an image that is being utilized in a computation for human assessment of accuracy.[21] Using the OS technique, the same MRI is entered into the algorithm hundreds more times, but each time with a slight modification – typically by systematically removing a subunit of the image, like a single pixel. Then, the

"likelihood of tumor" output is compared to the original image; if the modified image has a lower likelihood value than the original image, you can infer that the missing pixel was strongly associated with the tumor. This process is repeated multiple times, with each run removing a different pixel and assessing its impact on the tumor likelihood value. Then, a heat map can be generated and overlaid on the original MRI to highlight what regions of the image were most strongly associated with the tumor by the AI. The physician can then interpret the findings, use their experience, and evaluate whether the highlighted area is in fact likely a tumor. Appendix 3 visualizes a hypothetical workflow for how OS explanations in a program identifying dog breeds from an image can improve useability, accuracy, and trust.

Another model, LIME, uses a similar approach, in which it slightly changes the inputs and assesses how the output changes. However, using LIME, the model then attempts calculate a linear regression between how each new input and the matching output.[19] This allows LIME to then generate a series of numerical weights to convey how important each changed input may be. These weights could be used to generate a similar heat map to OS if the input was an image, but it also allows the user greater flexibility in the inputs it considers, including text. For example, if LIME were used in the above MRI example, it may be possible for it to additionally tell the physician how important factors from the patient's medical record (age, weight, sex, etc.) were to its interpretation of the MRI. While approaches like LIME may be more flexible, they do rely on simplifying the complex calculations of an AI/ML algorithm to simple linear equations, which may make it more prone to failure the further an individual case gets from the typical cases used in the algorithm's training set.

OS and other explainability methods have been utilized for applications such as identifying prostate cancer in histopathological samples, distinguishing lung diseases from a radiograph, predicting risk for psoriatic arthritis from the electronic health record, and more.[22-24] Beyond heat maps or other visualization tools, some tools can also provide simple written outputs (such as "clean margin") or link to data from its training set that the tool found to be most similar to the input. This provides an opportunity for the AI/ML user to utilize their own expertise in deciphering the accuracy of the output. While true explainability may never be possible for AI algorithms, models like OS, LIME, and Grad-CAM are promising efforts to make these systems more trustworthy. However, some experts in the field question: is explainability the right bar to hold AI to?[25]

*Other Black Boxes in Medicine*

When looking at other aspects of medicine, it is not uncommon to find black boxes or unclear processes that physicians and patients trust. For example, the analgesic mechanism for acetaminophen is not fully known and debated frequently in the literature, yet it is widely available over-the-counter in the United States.[26] Similarly, many genetic tests rely on genome wide association studies (GWAS), which often do not have a known, underlying biologic mechanism, but correlate certain genetic mutations with an increased risk of disease.[27] Yet these, and many other aspects of medicine, are routinely utilized in practice despite not truly being explainable, because they have been found to be safe and effective using rigorous scientific testing.

Randomized clinical trials (RCTs) are recognized as the gold standard or high level for evidence development in medicine, whether the intervention is explainable or not.[28] By carefully controlling variables and often utilizing a placebo, RCTs allow researchers, physicians, and regulators to best assess safety and efficacy of an intervention – but notably they do not necessitate a known mechanism of action, but often a theoretical hypothesis. When evaluating a new drug, the U.S. Food and Drug Administration (FDA) prefers, but ultimately does not require, a drugmaker to know how their drug works; they simply must prove that it is safe and effective for a specific

disease in its target population before approval.[29] True explainability may never be achievable for AI, but there is no reason to believe that an individual AI tool could not be found to be safe and effective using an appropriately designed RCT model. This raises the question as to why humans intrinsically view explainability for AI to be more important than in other black boxes or unexplainable processes in medicine, and if that will always remain a barrier to trust, but that philosophical debate reaches beyond the scope of this report.

Using explainability as a strict requirement for clinical adoption could additionally exclude applications of AI which rely on noticing patterns for which current medical knowledge cannot explain. The hypothetical examples described thus far in this report (antibiotic prescribing recommendations and image interpretation) describe devices that aim to improve or build upon current best practices in medicine. However, there are many researchers actively seeking to discover *new* methods or treatments from the vast amounts of medical data available. For example, one study used a ML algorithm to diagnose patients with type-2 diabetes mellitus (T2DM) based on recordings of their speech – a completely novel approach.[30] The authors of the study hypothesized several potential causes, such as the influence of blood glucose levels on vocal cord elasticity, or pitch modulation caused by myopathy, but as of writing, this correlation would be considered unexplainable using current medical knowledge. Despite that limitation, the authors reported over 70 percent accuracy in detecting T2DM just from audio recordings of a mere 11 words. Given the low level of invasiveness, low cost and prevalence of smart phones, similar tools could be desirable for routine screening applications despite the inability for patients and their physicians to comprehend how T2DM changes the voice. In those instances, transparency around the relative risks and benefits could be more useful for developing trust, which could be derived from a RCT.

## CURRENT REGULATORY APPROACHES

### *In Medicine*

As described in BOT 01-I-24, "Augmented Intelligence Development, Deployment, and Use in Health Care," the regulatory landscape for AI in the United States is inconsistent, and relevant health care regulatory agencies do not currently have a comprehensive strategy for oversight of AI. The FDA has been reviewing and approving algorithm-based devices since 1995, with over 1000 devices that utilize AI/ML being approved as of January 2025.[31] Applications for these devices vary, including triage and diagnostics, and cross multiple specialties.

In June 2024, the FDA, in collaboration with Health Canada and the United Kingdom's Medicines and Healthcare Products Regulatory Agency (MHRA), released their 10 guidelines for "good machine learning practice," which have been listed in Appendix 4.[32] These guidelines are non-binding, but give insight as to how regulators are thinking about AI oversight. None of the guidelines specifically mention explainability, however recommendations 7 ("Focus Is Placed on the Performance of the Human-AI Team"), and 9 ("Users Are Provided Clear, Essential Information") are generally supportive of the concept. Of note, under recommendation 9, device manufacturers are suggested to provide "the basis for decision-making when available." Interestingly, this phrasing could have two interpretations: (1) decision-making is not always present in AI tools, but an explanation is required whenever it is; or (2) explanations of decision-making are preferred, but ultimately not required if they are too complex to derive or no external explainability model is available. While ultimately the specific interpretation of this

recommendation is moot, as they are non-binding, it does underscore the level of uncertainty in potential regulations for explainability moving forward.

In January 2025, the FDA released a draft Guidance for Industry that has yet to be formalized at the time of writing.[33] In it, the FDA further describes the types of data they wish to see in submissions from AI tool developers. Within this guidance, the FDA describes explainability as a "risk control" to mitigate potential harm. Additionally, they further expound on explainability and visualization tools such as those described in this report, stating "[…] explainability tools or visualizations can be valuable in increasing model transparency and a user's confidence in a model's output and could be developed as part of the user interface. However, if not well designed and validated for the target user group, explainability tools or visualizations could also significantly mislead users. Therefore, sponsors should develop and validate explainability metrics and visualizations through appropriate testing." However, the guidance does not ultimate require explainability for a device submission.

In a scoping review of FDA-approved AI devices from 1995 to 2023 (692 total devices), researchers found that only 46 percent of device sponsors provided the FDA with the results of performance studies, and only 37 percent provided information on their testing sample size.[34] Given these gaps in disclosed information, the researchers concluded that "[their] current findings suggest that evaluation [of explainability] cannot be comprehensively conducted across approved FDA devices." A similar study, investigating 104 FDA-cleared AI tools to aid in medical imaging interpretation, found that less than half provided an explanation of their output.[35]

At the 2024 Interim Meeting of the House of Delegates, the AMA adopted policy stating that regulation should be "a risk-based approach where the level of scrutiny, validation, and oversight should be proportionate to the overall potential of disparate harm and consequences." While a lack of explainability does not increase the risk of a tool per se, removing a physician's ability to contextualize information from the output using their expertise should be considered a risk factor.

In 2024, the Assistant Secretary for Technology Policy/Office of the National Coordinator for Health Information Technology (ASTP/ONC) enacted policies to advance AI transparency through electronic health record (EHR) regulation, requiring disclosure of source attributes, data elements, and decision-making roles in AI technology embedded in EHRs. While not specifically focusing on explainability, ASTP/ONC's intent is to empower physicians to make informed choices, ensuring AI tools enhance rather than override clinical judgment. Eplainability is not explicitly mandated, yet ONC's emphasis on transparency will likely foster trust by clarifying how predictive models operate and assist physicians in interpreting AI outputs. These policies are intended to promote responsible AI adoption, reinforcing physician autonomy and incentivizing the development of fair, effective, and safe AI-driven tools in healthcare.

Some manufacturers and scholars have raised concerns that by disclosing or otherwise visualizing an explanation of AI computational processes, they may be exposing their intellectual property (IP) to competitors.[36,37] There remains ambiguity as to what is patentable with regards to AI-enabled medical devices. For example, the software driving the algorithm is generally patentable, as it is considered a finished product. However, the Supreme Court found in *Gottschalk v. Benson* that mathematical formulas are generally not patentable as they represent abstract concepts, which leave algorithms unprotected.[38] In a January 2025 report on AI and copyrightability, the U.S. Copyright Office concluded that current laws and regulations adequately address AI copyright concerns, and did not recommend any legislative changes.[39] The recent release of the Chinese-based AI DeepSeek has highlighted the difficulty in protecting IP in the rapidly growing AI/ML space. Briefly, the American-based company OpenAI claim that DeepSeek developers used the outputs of

OpenAI models to reverse engineer or otherwise train a model that would be a market competitor.[40] While explanations of AI/ML tool outputs make the outputs more trusted, they may also make the underlying system more vulnerable to rival companies.

As such, other fields which have utilized algorithms (like banking and finance) rely on a "trade secrets" model for protecting their IP, in which algorithms are deemed proprietary and are hidden from the user. This is a similar approach to how food manufacturers protect their recipe yet disclose their ingredients for food products. However, if this approach were to continue, medical AI developers may be pitting innovation against a patient's right to transparency and autonomy in their medical decision-making.

*Outside of Medicine*

Given the rapid expansion of AI, other fields grapple with similar issues of explainability in their regulatory oversight. For example, the Equal Credit Opportunity Act of 1974 requires that financial institutions provide written descriptions explaining why they made an adverse decision (such as denying a loan application), and explicitly protecting certain traits (such as race or sex) from being the basis for those decisions. However, as financial institutions began incorporating more and more automated AI tools in their decision-making, explanations for adverse decisions became increasingly more abstract, and many worried that protected traits were being used by black box algorithms.

In response, the Consumer Financial Protection Bureau (CFPB) released a memo in 2023 clarifying that even in instances where black box AI tools "[made] it difficult — if not impossible — to accurately identify the specific reasons for denying credit or taking other adverse actions," customers are still legally owed an explanation of those specific reasons they were denied, and thus does not permit unexplainable algorithms to be used.[41] The CFPB went further, stating that even estimations or proxies of the AI tool's logic may not be acceptable if they are not specific enough. For example, if a financial institution did not know the logic their AI tool used to make decisions, a simple explanation of "the applicant has insufficient income" would be deemed inadequate. This approach mirrors legislation in states such as Colorado, New York, California, and Connecticut, which limit insurance companies' ability to use unexplainable, black box algorithms when making insurance coverage determinations.[42]

Outside the United States, the European Union's 2018 General Data Protection Regulation (GDPR) is generally regarded as one of the first attempts at comprehensive regulations of AI and other digital technologies and is the basis for many international regulations. The GDPR contains several regulations for the development and use of algorithms, but its position on explainability is less clear. Under Article 15 of the GDPR, it states that algorithms are required to disclose "meaningful information about the logic involved, as well as the significance and the envisaged consequences of such processing for the data subject."[43] Some scholars have interpreted this text to mean that the GDPR establishes a "right to explanation," however this right has yet to be asserted and adjudicated in a European court.[44]

*Additional Considerations*

When regulating the explainability of AI, it is critical to establish both who is owed an explanation, and where the explanation comes from. In the medical context, there are several potential audiences, such as the physician, the patient, or external groups such as payors. If, for example, a

"right to explanation" was proposed – who has the right? In the United States, the Health Insurance Portability and Accountability Act (HIPAA) generally establishes that patients have a right to access their clinical data.[45] However, as discussed above, there are significant gaps in the ability of most AI tools to explain their outputs in a layperson fashion, and most models to approximate explanations (such as OS, LIME, and Grad-CAM) are targeted to a physician-type expert for contextualization and action.

When discussing the disclosure of test results, the Code of Medical Ethics states that "[test] results [should be] conveyed sensitively, in a way that is understandable to the patient/surrogate, and the patient/surrogate receives information needed to make well-considered decisions about medical treatment and give informed consent to future treatment[.]" In a hypothetical situation where a physician receives an AI tool's explanation, but then uses their own words to convey that information to their patient, it is unclear if that would suffice under some scholarly interpretations of a GDPR-styled "right to explanation."

CURRENT AMA POLICY

The AMA maintains extensive policy on AI generally. Board of Trustees (BOT) Report 15-I-24, "Augmented Intelligence Development, Deployment, and Use in Health Care," provided a comprehensive overview of the regulatory landscape and the AMA's history in AI governance. A brief summary of relevant sections of AMA policies are as follows (full text of policy available at the end of this report):

H-480.931, "Assessing the Intersection Between AI and Health Care"

- "Health care AI must be designed, developed, and deployed in a manner which is ethical, equitable, responsible, accurate, and transparent."
- "Health care AI requires a risk-based approach where the level of scrutiny, validation, and oversight should be proportionate to the overall potential of disparate harm and consequences the AI system might introduce."
- "Clinical decisions influenced by AI must be made with specified human intervention points during the decision-making process. As the potential for patient harm increases, the point in time when a physician should utilize their clinical judgment to interpret or act on an AI recommendation should occur earlier in the care plan. With few exceptions, there generally should be a human in the loop when it comes to medical decision making capable of intervening or overriding the output of an AI model."
- "Medical specialty societies, clinical experts, and informaticists are best positioned and should identify the most appropriate uses of AI-enabled technologies relevant to their clinical expertise and set the standards for AI use in their specific domain."
- "Purchasers and/or users (physicians) should carefully consider whether or not to engage with AI-enabled health care technologies if […] information is not disclosed by the developer. As the risk of AI being incorrect increases risks to patients (such as with clinical applications of AI that impact medical decision making), disclosure of […] information becomes increasingly important."
- "Individuals impacted by a payor's automated decision-making system, including patients and their physicians, must have access to all relevant information (including the coverage criteria, results that led to the coverage determination, and clinical guidelines used)."

H-480.939, "Augmented Intelligence in Health Care"

- "Oversight and regulation of health care AI systems must be based on risk of harm and benefit accounting for a host of factors, including but not limited to: intended and

reasonably expected use(s); evidence of safety, efficacy, and equity including addressing bias; AI system methods; level of automation; transparency; and, conditions of deployment."

- "Physicians should not be penalized if they do not use AI systems while regulatory oversight, standards, clinical validation, clinical usefulness, and standards of care are in flux."
- "[Our AMA will advocate that] AI is designed to enhance human intelligence and the patient-physician relationship rather than replace it."

H-480.940, "Augmented Intelligence in Health Care"

- "[Our AMA will seek to promote] development of thoughtfully designed, high-quality, clinically validated health care AI that […] is transparent[.]"

## CONCLUSION

Ironically, the concept of explainability is hard to explain. It is complex, nuanced, and asks profound questions on human cognition and the meaning of trust. While this report primarily focused on hypothetical instances where AI/ML performs poorly to highlight the opportunities and challenges for explainability, the responsible usage of well-designed AI/ML tools has already had a profoundly transformative impact on medicine, building efficiency in practice, increasing the breath of data integration, and increasing communication capabilities, such as the use of a LLM. The appeal and need for some level of explainability for AI/ML tools in medicine is clear, where decisions can have life or death consequences. Physicians are trained to utilize a broad compilation of information for medical decision-making, including context and seeing the whole patient's clinical picture; a binary "yes/no" output from an AI/ML tool is restrictive and lacks nuance.

However, explainability struggles in practice in part due to the disconnect between how humans and computers process information. AI does not think, nor can it guess, infer, or intuit, all of which are core processes for how a physician would make a clinical determination. Some models, such as occlusion sensitivity, are being developed to allow for insight into the inner workings of an AI tool, but they generally still require expert interpretation, and risk being an oversimplification of the true computational process.

Medicine is experienced in handling unexplainable phenomena and utilizing data through research and evaluation verify safety and efficacy. Understanding the mechanism of action of a drug, biologic process, or otherwise is crucial for building trust, troubleshooting, and advancing medical practice, but it generally has not been the barrier to clinical *entry*. By the same token, however, physicians should feel confident that the tools they use in the clinic are safe, based on sound science, and can be discussed appropriately with their patients, so they can engage in shared decision-making.

## RECOMMENDATIONS

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

1. To maximize the impact and trustworthiness of augmented intelligence and machine-learning (AI/ML) tools in clinical settings, our AMA recognizes that:
    a. Explainable AI with safety and efficacy data should be the expected form of AI tools for clinical applications, and exceptions should be rare and require at minimum safety and efficacy data prior to their adoption or regulatory approval.

b. To be considered "explainable," an AI device's explanation of how it arrived at its output must be interpretable and actionable by a trained expert. Claims that an algorithm is explainable should be adjudicated only by independent third parties, such as regulatory agencies or appropriate specialty societies, rather than by declaration from its developer.
c. Explainability should not be used as a substitute for other means of establishing safety and efficacy of AI tools, such as through randomized clinical trials.
d. Concerns of intellectual property (IP) infringement, when provided as rationale for not explaining how an AI device created its output, does not nullify a patient's right to transparency and autonomy in medical decision-making. While intellectual property should be afforded a certain level of protection, concerns of infringement should not outweigh the need for explainability for AI with medical applications. (New HOD Policy)

2. That our American Medical Association will collaborate with experts and interested parties to develop and disseminate a list of definitions for key concepts related to medical AI and its oversight. (Directive to Take Action)

3. That policies H-480.931, "Assessing the Intersection Between AI and Health Care," H-480.939, "Augmented Intelligence in Health Care," and H-480.940, "Augmented Intelligence in Health Care" be reaffirmed. (Reaffirm HOD Policy)

Fiscal Note – less than $1000

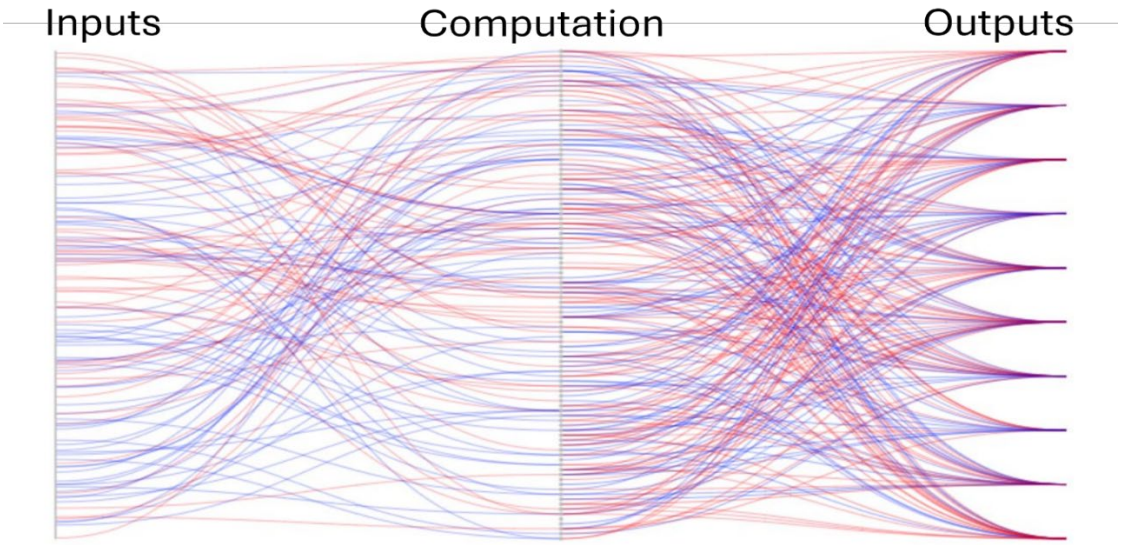
APPENDIX

*Appendix 1 – Sample AI Explainability*

(a) Husky classified as wolf (b) Explanation

Appendix 1 – A sample of an AI system processing an image (left) and providing an explanation (right) for how it determined whether the input was a picture of a husky or a wolf. In this case, the system mistook a husky for a wolf due to the presence of snow, which was present in most images of wolves used for the AI's training set.

*Appendix 2 – Visualization of Neural Networks*




Appendix 2 – Visualization of the complexity in a sample neural network used to detect the digits 0 through 9 from handwriting samples. Each line on the left side represents an input considered by the algorithm, and each position on the right side represents a potential output (the digits 0 through 9). The middle visualizes the interconnectivity and how the algorithm sorts inputs into outputs. Image adapted from https://www.i-am.ai/neural-numbers.html.

*Appendix 3 – Sample Occlusive Sensitivity Workflow*

## INPUT

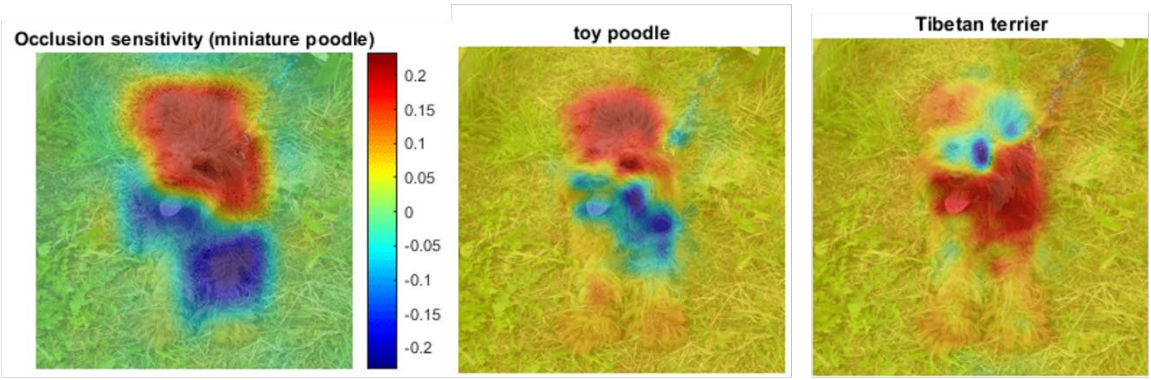
User inputs image of a poodle / cocker spaniel mixed breed dog, and asks AI tool to estimate the breed

## OUTPUT

**Breed Scores**
Miniature Poodle: 23%
Toy Poodle: 17%
Tibetan Terrier: 11%

AI tool outputs ranked scores of dog breeds, struggling to identify the dog's breed. The user wants to troubleshoot and wonders if the dog is blending in with the grass.

## OCCLUSION SENSITIVITY "EXPLANATION"




In these images, red coloration indicates the portions of the image that contributed more heavily to the breed's score. The user could thus infer that the algorithm is correctly differentiating grass from fur. However, in the miniature and toy poodle images, the back is likely incorrectly being grouped with the top of the head. The user discards the results and picks a new image from a different angle.

Apendix 3 – Hypothetical workflow of a user using an AI/ML tool to identify a dog breed. By using occlusion sensitivity, the user can identify that the tool was mischaracterizing key body features, thus explaining the poor results but allowing the user to modify their input to improve accuracy. Images adapted from https://www.mathworks.com/help/deeplearning/ug/understand-network-predictions-using-occlusion.html.

*Appendix 4 – FDA Good Machine Learning Practice for Medical Device Development: Guiding Principles*

Taken from: https://www.fda.gov/medical-devices/software-medical-device-samd/good-machine-learning-practice-medical-device-development-guiding-principles

1. **Multi-Disciplinary Expertise Is Leveraged Throughout the Total Product Life Cycle:** In-depth understanding of a model's intended integration into clinical workflow, and the desired benefits and associated patient risks, can help ensure that ML-enabled medical devices are safe and effective and address clinically meaningful needs over the lifecycle of the device.
2. **Good Software Engineering and Security Practices Are Implemented:** Model design is implemented with attention to the "fundamentals": good software engineering practices, data quality assurance, data management, and robust cybersecurity practices. These practices include methodical risk management and design process that can appropriately capture and communicate design, implementation, and risk management decisions and rationale, as well as ensure data authenticity and integrity.
3. **Clinical Study Participants and Data Sets Are Representative of the Intended Patient Population:** Data collection protocols should ensure that the relevant characteristics of the intended patient population (for example, in terms of age, gender, sex, race, and ethnicity), use, and measurement inputs are sufficiently represented in a sample of adequate size in the clinical study and training and test datasets, so that results can be reasonably generalized to the population of interest. This is important to manage any bias, promote appropriate and generalizable performance across the intended patient population, assess usability, and identify circumstances where the model may underperform.
4. **Training Data Sets Are Independent of Test Sets:** Training and test datasets are selected and maintained to be appropriately independent of one another. All potential sources of dependence, including patient, data acquisition, and site factors, are considered and addressed to assure independence.
5. **Selected Reference Datasets Are Based Upon Best Available Methods:** Accepted, best available methods for developing a reference dataset (that is, a reference standard) ensure that clinically relevant and well characterized data are collected and the limitations of the reference are understood. If available, accepted reference datasets in model development and testing that promote and demonstrate model robustness and generalizability across the intended patient population are used.
6. **Model Design Is Tailored to the Available Data and Reflects the Intended Use of the Device:** Model design is suited to the available data and supports the active mitigation of known risks, like overfitting, performance degradation, and security risks. The clinical benefits and risks related to the product are well understood, used to derive clinically meaningful performance goals for testing, and support that the product can safely and effectively achieve its intended use. Considerations include the impact of both global and local performance and uncertainty/variability in the device inputs, outputs, intended patient populations, and clinical use conditions.
7. **Focus Is Placed on the Performance of the Human-AI Team:** Where the model has a "human in the loop," human factors considerations and the human interpretability of the model outputs are addressed with emphasis on the performance of the Human-AI team, rather than just the performance of the model in isolation.
8. **Testing Demonstrates Device Performance during Clinically Relevant Conditions:** Statistically sound test plans are developed and executed to generate clinically relevant device performance information independently of the training data set. Considerations include the intended patient population, important subgroups, clinical

environment and use by the Human-AI team, measurement inputs, and potential confounding factors.

9. **Users Are Provided Clear, Essential Information:** Users are provided ready access to clear, contextually relevant information that is appropriate for the intended audience (such as health care providers or patients) including: the product's intended use and indications for use, performance of the model for appropriate subgroups, characteristics of the data used to train and test the model, acceptable inputs, known limitations, user interface interpretation, and clinical workflow integration of the model. Users are also made aware of device modifications and updates from real-world performance monitoring, the basis for decision-making when available, and a means to communicate product concerns to the developer.
10. **Deployed Models Are Monitored for Performance and Re-training Risks are Managed:** Deployed models have the capability to be monitored in "real world" use with a focus on maintained or improved safety and performance. Additionally, when models are periodically or continually trained after deployment, there are appropriate controls in place to manage risks of overfitting, unintended bias, or degradation of the model (for example, dataset drift) that may impact the safety and performance of the model as it is used by the Human-AI team.

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REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 9-A-25

Subject: Rare Disease Advisory Councils

Presented by: John T. Carlo, MD, MS, Chair

Referred to: Reference Committee E

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## INTRODUCTION

Resolution 231-A-24, "Supporting the Establishment of Rare Disease Advisory Councils," was referred by the House of Delegates (HOD). It stated that "that our American Medical Association will support state legislation for the establishment of Rare Disease Advisory Councils in each state." While there was general support for Rare Disease Advisory Councils (RDACs), there was some concern expressed in testimony regarding the undue influence of pharmaceutical companies and the need to help ensure the participation of appropriate physician specialists. This report serves as the Council on Science and Public Health's response to that referral.

## METHODS

English language articles were selected from searches of PubMed and Google Scholar using the search terms "rare disease advisory councils." Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by government agencies and applicable organizations were also reviewed for relevant information.

## BACKGROUND

In the United States, the term "rare disease" is defined by the Orphan Drug Act of 1983 to mean any disease which impacts fewer than 200,000 people in the country.[1] Despite its name, an estimated 1-in-10 Americans will be diagnosed with a rare disease in their lifetime. Conditions covered by the Orphan Drug Act span from those that are well-studied, such as cystic fibrosis or amyotrophic lateral sclerosis (ALS), to the highly obscure, such as CANDLE syndrome, of which there have only been 30 recorded cases in the world.[2,3] Per a 2024 landscape analysis, approximately 80 percent of rare diseases are believed to be genetic in origin with 70 percent presenting in childhood.[4]

Patients with rare diseases face many unique obstacles to care. First, patients with rare diseases often experience significant delay between symptom onset and a diagnosis, known as the "diagnostic odyssey."[5] Rare disease patient groups estimate that the *average* diagnostic odyssey length is six years, requires an average of seven specialist visits, and typically costs $220,000 from medical expenses and reduced ability to work.[6]

Once a diagnosis has been made, patients may then further struggle to access the care they need. Currently, less than five percent of all rare diseases have a medication approved by the U.S. Food and Drug Administration (FDA).[4] Of those that do, many are amongst the most expensive therapies

on the market. Per one analysis, 8 of the 10 most expensive drugs in the United States treat rare diseases.[7] For example, an FDA-approved gene therapy for spinal muscular atrophy (SMA), onasemnogene abeparvovec (brand name Zolgensma), costs approximately $2.1 million per dose, which at the time of its FDA approval, set the record for the world's most expensive drug.[8] Given the price tag, access, and coverage to treatment for SMA patients has resulted in ethical controversies. For example, Zolgensma's manufacturer Novartis utilizes a medication lottery to give out 100 doses each year at random.[9] In Brazil, governmental drug reimbursement analysis recommended that the Brazilian government should pay 77 percent less than the manufacturer's price, resulting in Novartis withdrawing Zolgensma from Brazilian markets and subsequent lawsuits.[10]

Additionally, rare disease specialty care can often be geographically centralized, resulting in patients having to travel long distances for care. A study in Europe found that 25 percent of rare disease patients have to leave their geographic region to receive care, with 2 percent having to leave their country entirely.[11]

In a system where resources are limited, investing in research and development for treatments of rare diseases can be too risky and inefficient for some companies. By definition, an individual rare disease has few patients, resulting in fewer opportunities for a company to recoup its investment, but also creates challenges in the design and implementation of clinical trials for recruiting and allocating patients. Clinical trials for rare disease treatments have lower enrollment, and therefore are frequently designed to utilize more nonrandomized, unblinded trial designs or to measure surrogate endpoints rather than patient-centered clinical outcomes. These trial designs, although often necessary in smaller studies, limit regulators' confidence in researchers' efficacy and safety conclusions.[12] As a result, there is an ongoing debate around the development and approval of treatments for rare disease: how can rare disease treatments be given the regulatory flexibility they need around clinical trial design, while avoiding providing patients with false hope at an ultra-high price point?[13]

## RARE DISEASE ADVISORY COUNCILS

Given the complexities, nuances, and equity concerns when allocating resources for patients with rare diseases, many state governments have opted to utilize RDACs to provide guidance. The first RDAC was established by the North Carolina legislature in 2015, and while composition of the Council has evolved over time, it currently consists of:[14]

- two physicians,
- one registered nurse,
- one academic researcher,
- a hospital administrator,
- two adults diagnosed with a rare disease,
- two caregivers for patients with rare diseases,
- one representative from a patient advocacy group,
- one pharmacist,
- one member of a pharmaceutical or life sciences company developing rare disease treatments,
- two representatives of payors,
- a genetic counselor,
- and three personal appointees of elected officials

Compositions of RDACs vary from state-to-state but generally have a similar cross-section of representatives. Currently 27 states have formed a RDAC, and at least two others have approved legislation to establish one.[15] After manual review of the current landscape of state authorizing legislation, no RDAC currently requires the participation of a medical ethicist, which could provide value.

RDACs may have different requirements but generally are enacted to provide guidance for the state legislature and its executive branch. RDACs tend to focus on state-level barriers to access, such as reimbursement from state Medicaid or other state-regulated insurance programs, protecting and/or expanding newborn screening programs, out-of-pocket drug prices, telehealth flexibilities, easing of step therapy requirements, and access to medical nutrition, which many rare metabolic syndromes require.[16-18] Other functions of RDACs may include advocacy for research funding, performing state-wide needs assessments, maintaining rare disease patient registries, creating awareness campaigns for clinical trial recruitment, or collaborating with academic centers to align research priorities.

*Influence of Pharmaceutical Companies*

To help understand the influence of pharmaceutical companies on the outputs of an RDAC, a review of their authorizing laws was conducted (summarized in Appendix). Of the 27 states with an RDAC, only one state (Ohio) had more voting seats designated for pharmaceutical industry representatives than physicians. In that state, the overall voting power of pharmaceutical industry representatives was low (two of 25 total votes, or eight percent of voting share). Nine states had zero voting seats designated for pharmaceutical company representatives.

It should also be noted that this analysis may not represent the actual make-up of any given state's RDAC. Several positions delineated by state law (such as hospital administrator or academic researcher) could also be filled by a licensed physician or someone from a pharmaceutical company. For example, the state of Pennsylvania calls for three physicians and two pharmaceutical industry representatives. However, when looking at the membership of their RDAC (as of January 2025), there are eight members with MD or DO credentials, and an additional policy specialist from the state's medical society.[19] One of the two pharmaceutical industry representatives has been filled by a member of a manufacturer's patient advocacy group. However, it is also difficult to ascertain the level of financial involvement that members have with the pharmaceutical industry, given the intertwined nature of medical research. Despite these limitations, there has been no evidence identified which would suggest that commercial interests have had an outsized, undue, or otherwise problematic influence on the work of RDACs to date, although the risk still exists.

RDACs can also provide an informational venue for representatives to receive scientific and technical knowledge from scientists from the pharmaceutical industry. The risk/reward balance of investing in rare diseases can often result in pharmaceutical companies simply choosing to avoid developing treatments. Additionally, there are serious difficulties in the recruitment and powering clinical trials for rare diseases, which are the kinds of issues that legislatures should be made aware of. By providing a venue for industry to interface with other interested parties, it gives an opportunity for patient advocates and their physicians to have a larger voice in guiding research priorities. Finally, when treatments are available, legislators need to be able to hear about the benefits and make tough decisions when looking to cover the sometimes-ultra-costly rare disease treatments.

CURRENT AMA POLICY

AMA Policy, H-460.880 "Recognizing the Burden of Rare Disease" recognizes the under-diagnosis, under-treatment, and financial burden of rare disease to the health care system and affected individuals. The policy notes the AMA's support of efforts to increase awareness of patient registries, improve diagnostic and genetic tests and incentivize drug and device companies to develop novel treatments.

More broadly, our AMA also generally supports physician participation in decision-making bodies where possible. For example, H-225.983 "Physician Representation on Hospital Governing Boards" and H-405.953 "Participation of Physicians on Healthcare Organization Boards" encourage physician membership in advisory boards and note that conflict-of-interest policies should be robust.

CONCLUSION

Ensuring that patients with rare diseases have access to the diagnosis, specialists, and treatments they need is a delicate balancing act. States may struggle to identify who and what conditions require prioritization within their borders and often benefit from external advisement. Rare Disease Advisory Councils (RDACs) are a useful tool for states and other entities to adopt to provide a wide array of voices for decision makers. It should be noted that while the original resolution sought support for solely state-based RDACs, it is possible that similarly beneficial groups could exist in other forms, including municipal, regional, multi-state, or federal.

After reviewing the current landscape, there has been no evidence to suggest that those with monetary interests have an outsized or unethical voice in RDACs, but legislatures should be cognizant of the risk and include appropriate guardrails to maintain the goal of RDACs serving the public interest. With such guardrails in place, RDACs provide the opportunity to best support patients with rare disease by removing barriers across the spectrum, from diagnosis to reimbursement.

RECOMMENDATIONS

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

That Policy H-460.880, "Recognizing the Burden of Rare Disease" be amended by addition to read as follows:

H-460.880, "Recognizing the Burden of Rare Disease"

1. Our American Medical Association recognizes the under-treatment and under-diagnosis of orphan diseases, the burden of costs to health care systems and affected individuals, and the health disparities among patients with orphan diseases.
2. Our AMA supports efforts to increase awareness of patient registries, to improve diagnostic and genetic tests, and to incentivize drug companies and medical device companies to develop novel therapeutics and devices to better understand and treat orphan diseases.
3. Our AMA supports the study, approval, and coverage of implantable medical devices and therapeutics via FDA Humanitarian Device Exemption for treatment of orphan diseases.
4. <u>Our AMA supports the establishment of Rare Disease Advisory Councils to inform policymakers and other interested parties about the unique challenges faced by patients</u>

with rare diseases and their caregivers. Rare Disease Advisory Councils should include voting representation from patients with rare disease and physicians who specialize in the diagnosis and/or treatment of rare disease, among other interested parties.

5. Our AMA recommends Rare Disease Advisory Councils should develop guidance on management of conflicts of interest (especially financial conflicts) and appropriate conditions for recusal from discussions and decisions. (Modify Current HOD Policy)

Fiscal Note – less than $1000

APPENDIX – OVERVIEW OF PHYSICIAN AND PHARMACEUTICAL INDUSTRY MEMBERSHIP OF RDACS

| State | Total RDAC Members | Number of Physicians* (%) | Number of Pharmaceutical Industry (%) |
|---|---|---|---|
| **Alabama** | 17 | 6 (35%) | 0 (0%) |
| **Colorado** | 12 | 2 (17%) | 1 (8%) |
| **Connecticut** | 12 | 2 (17%) | 1 (8%) |
| **Delaware** | 14 | 2 (14%) | 1 (7%) |
| **Florida** | 22 | 3 (14%) | 1 (5%) |
| **Georgia** | 16 | 3 (19%) | 1 (6%) |
| **Illinois** | 11 | 3 (27%) | 0 (0%) |
| **Indiana** | 15 | 1 (7%) | 1 (7%) |
| **Kentucky** | 20 | NR | NR |
| **Louisiana** | 12 | 3 (25%) | 0 (0%) |
| **Maine** | 20 | 4 (20%) | 1 (5%) |
| **Maryland** | 21 | 2 (10%) | 1 (5%) |
| **Massachusetts** | 28 | 3 (11%) | 2 (7%) |
| **Minnesota** | 24 | 4 (17%) | 1 (4%) |
| **Missouri** | 11 | 6 (55%) | 0 (0%) |
| **Nevada** | 15 | 3 (20%) | 0 (0%) |
| **New Hampshire** | 11 | 1 (9%) | 0 (0%) |
| **New Jersey** | 20 | 2 (10%) | 1 (5%) |
| **New York** | NR | NR | NR |
| **North Carolina** | 21 | 2 (10%) | 1 (5%) |
| **Ohio** | 25 | 1 (4%) | 2 (8%) |
| **Pennsylvania** | 24 | 3 (13%) | 2 (8%) |
| **South Carolina** | 11 | 1 (9%) | 1 (9%) |
| **Tennessee** | 11 | 3 (27%) | 0 (0%) |
| **Utah** | 16 | 5 (31%) | 0 (0%) |
| **Virginia** | 21 | 3 (14%) | 1 (5%) |
| **West Virginia** | 11 | 3 (27%) | 0 (0%) |

NR = No Restriction

* = Includes positions described as board-certified geneticists

CITED AMA POLICY

**Recognizing the Burden of Rare Disease H-460.880**

1. Our American Medical Association recognizes the under-treatment and under-diagnosis of orphan diseases, the burden of costs to health care systems and affected individuals, and the health disparities among patients with orphan diseases.
2. Our AMA supports efforts to increase awareness of patient registries, to improve diagnostic and genetic tests, and to incentivize drug companies and medical device companies to develop novel therapeutics and devices to better understand and treat orphan diseases.
3. Our AMA supports the study, approval, and coverage of implantable medical devices and therapeutics via FDA Humanitarian Device Exemption for treatment of orphan diseases.

**Physician Representation on Hospital Governing Boards H-225.983**

1. It is the policy of the AMA that physicians who are members of the medical staff shall be eligible for, and should be included in, full membership on hospital governing bodies and their action committees in the same manner as are other knowledgeable and effective individuals. Other physicians also should be considered eligible for membership on the governing body. The hospital medical staff should have the right of representation at all meetings of the governing body by medical staff members elected by the medical staff having the right of attendance, voice and vote. Compensation to medical staff members for service to the hospital should not preclude the physician's membership on the hospital governing board.
2. Hospital conflict of interest policies should include physician medical staff members of hospital governing boards.

**Participation of Physicians on Healthcare Organization Boards H-405.953**

1. Our American Medical Association will advocate for and promote the membership of physicians on the boards of healthcare organizations including, but not limited to, acute care providers; insurance entities; medical device manufacturers; and health technology service organizations.
2. Our AMA will promote educational programs on corporate governance that prepare and enable physicians to participate on health organization boards.
3. Our AMA will provide physicians, the public, and health care organizations information on the positive impact of physician leadership.

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 501
(A-25)

Introduced by: American Academy of Otolaryngology – Head and Neck Surgery

Subject: Safer Button / Coin Batteries

Referred to: Reference Committee E

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Whereas, button, or coin cell, batteries can lead to life-threatening injuries of the esophagus, trachea or major vasculature in children when ingested[1-3]; and

Whereas, button batteries are in ubiquitous use in household items such as remote controls, toys, decorations and key fobs; and

Whereas, no battery manufacturer currently produces a safe button or coin cell battery; and

Whereas, it is estimated that a child is taken to the emergency room every 75 minutes with a battery-related injury, a rate that has doubled within the last decade[3]; and

Whereas, the American Academy of Otolaryngology-Head and Neck Surgery, the American Academy of Pediatrics, the American College of Surgeons and nine other medical organizations have joined to call on battery manufacturers to introduce safer alternatives to current button batteries[5]; therefore be it

RESOLVED, that our American Medical Association promote a definition of safer button or coin cell battery as one which will not cause significant tissue injury if lodged in the body but will still adequately function to power electronic devices (New HOD Policy); and be it further

RESOLVED, that our AMA advocate for industry development and employment of safer button battery technology. (Directive to Take Action)

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

Received: 4/14/25


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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 502
(A-25)

Introduced by: American College of Rheumatology, American Academy of Physical Medicine and Rehabilitation, American Psychiatric Association, American Society of Gastrointestinal Endoscopy, American College of Physicians, American Academy of Allergy, Asthma, and Immunology

Subject: NIH Grant Funding for Medical Research

Referred to: Reference Committee E

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Whereas, in February 2025, the National Institutes of Health (NIH) issued a notice (NOT-OD-25-068) stating it would cap indirect cost rates for all NIH grants at 15%, replacing the previously negotiated rates; and

Whereas, NIH grant funding plays a crucial role in advancing medical research and has historically supported negotiated indirect cost rates averaging nearly 30% at research universities, with some institutions having rates exceeding 50% or even 60%, which are essential for sustaining critical research infrastructure; and

Whereas, chronic diseases, including rheumatoid arthritis, lupus, psoriatic arthritis, scleroderma, and others, have high prevalence, chronicity, and disability burdens on both patients and healthcare systems, but research on them is often underfunded relative to their impact; and

Whereas, current levels of NIH funding of medical research are already not sufficient to address the growing needs and unmet challenges in chronic diseases; and

Whereas, such drastic cuts risk upending the paradigm that underpins American leadership in medical research; and

Whereas, direct costs are expenditures directly attributable to a specific research project (such as salaries, equipment, and supplies), while indirect costs (also known as facilities and administrative (F&A) costs) fund the essential infrastructure and administrative support necessary for effective research; moreover, indirect cost rates—calculated as the ratio of indirect costs to direct costs—are negotiated between research institutions and the NIH (or other federal grant organizations); and

Whereas, indirect costs help fund the infrastructure that makes research possible, which includes laboratories and equipment, utilities and maintenance, computational resources, and administrative support; and

Whereas, indirect costs help maintain institutional support for medical research by enabling the hiring and training of research staff and personnel; and

Whereas, indirect costs enable researchers to effectively manage the legal and regulatory frameworks that govern research and clinical trial monitoring; and

Whereas, indirect costs help ensure continuity in medical research, which often requires long-term commitment, as many diseases are chronic and involve complex, multi-phase studies; and

Whereas, indirect costs facilitate collaboration, which is often vital in complex medical fields that involve multidisciplinary approaches, including immunology, genetics, pharmacology, and clinical care; and

Whereas, without adequate indirect funding, it would be difficult for researchers to access the resources necessary to carry out the full scope of research needed to improve the understanding, treatment, and care of patients with chronic diseases; and

Whereas, small research institutions rely on indirect funds to support key staff whose costs could be spread across more grants at larger institutions; and

Whereas, large research institutions will also be significantly impacted by cuts to indirect costs due being located in high cost areas; and

Whereas, indirect costs represent an investment in the research infrastructure that underpins high-risk, innovative, and early-stage investigations, and are critical for sustaining both established and independent research initiatives; and

Whereas, recent research indicates that investigators spend approximately 42% of their time on administrative compliance, a burden compounded by an expanding web of federal regulations that diverts valuable resources from research, thereby necessitating regulatory reforms that could safely reduce unnecessary administrative overhead without compromising research quality; therefore be it

RESOLVED, that our American Medical Association will work with the National Institutes of Health (NIH) and other relevant stakeholders to 1) oppose caps on indirect costs, including facilities and administrative reimbursements, in federal grants (including NIH grants) or any funding policy that restricts critical early-stage and independent research, and 2) protect the ability of research institutions to negotiate indirect cost rates to ensure researchers can recover the full cost of conducting federally funded research (Directive to Take Action); and be it further

RESOLVED, that our AMA will advocate for targeted reforms to streamline administrative and regulatory requirements in order to achieve sustainable cost reductions while preserving essential research infrastructure. (Directive to Take Action)

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

Received: 4/22/25

**RELEVANT AMA POLICY**

**Funding of Biomedical, Translational, and Clinical Research H-460.926**
Our AMA: (1) reaffirms its long-standing support for ample federal funding of medical research, including basic biomedical research, translational research, clinical research and clinical trials, health services research, outcomes research, and prevention research; and (2) encourages the National Institutes of Health, the Agency for Healthcare Research and Quality and other appropriate bodies to develop a mechanism for the continued funding of translational research.
Sub. Res. 507, I-97; Reaffirmed: CSA Rep. 13, I-99; Modified: Res. 503, and Reaffirmation A-00; Modified: CSAPH Rep. 1, A-10; Reaffirmed: CSAPH Rep. 01, A-20

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 503
(A-25)

Introduced by: Colorado Delegation

Subject: Safeguarding Neural Data Collected by Neurotechnologies

Referred to: Reference Committee E

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Whereas, neurotechnologies refer to devices capable of recording, interpreting, or altering the response of an individual's central or peripheral nervous system to its internal or external environment[1]; and

Whereas, neural data captured by neurotechnologies is information coming from the measurement of the activity of the central or peripheral nervous system, is extremely sensitive, and can reveal intimate information about individuals, including information about health, mental states, emotions, and cognitive functioning[2]; and

Whereas, rapid advances in neurotechnologies present great promise and potential risks but have also outpaced regulatory governance at all levels[1]; and

Whereas, neurotechnologies have long been used in medical and research contexts but are rapidly being developed and deployed outside clinical settings[3]; and

Whereas, consumer neurotechnology products have a range of health-related applications, including at-home treatment for ADHD, anxiety, depression, and other mental disorders[4]; and

Whereas, consumer neurotechnology products are generally medical-grade but are not regulated as medical devices, nor is the data they collect protected under the Health Insurance Portability and Accountability Act (HIPAA) or state health data privacy laws[1]; and

Whereas, the growth of the consumer neurotechnology market will contribute to the building of enormous datasets of neural data that will allow for longitudinal insights about both patients and consumers; and

Whereas, consumer neurotechnologies and the data they collect will unlock new insights into brain health when integrated into clinical research; and

Whereas, neurotechnologies raise particularly pressing privacy concerns given their ability to monitor, decode, and manipulate neural activity; and

Whereas, boundaries must be developed to prohibit neurotechnologies from disrupting individual identity and sense of self[5]; and

Whereas, individuals must also have ultimate control over their own decision-making, without manipulation by neurotechnologies[5]; and

Whereas, the principle of non-discrimination should be built into algorithms for the development and application of neurotechnologies[6]; and

Whereas, there should be established guidelines, based on principles of justice and fair access, for regulating neurotechnologies that provide mental augmentation; therefore be it

RESOLVED, that our American Medical Association recognizes and supports the extraordinary developments in neurotechnologies and the promise they hold for building understanding of how the brain and nervous system work, for the treatment and curing of neurological diseases, and for helping all people achieve their maximum potential (New HOD Policy); and be it further

RESOLVED, that our AMA support legislative and regulatory efforts to protect patients and all people in the United States from risks to mental privacy, identity, and agency, as well as from discrimination and inequality that may be caused by neurotechnologies (New HOD Policy); and be it further

RESOLVED, that our AMA reaffirm that neural data is information obtained by measuring the activity of a person's central or peripheral nervous system through the use of neurotechnologies and neural data does not include inferential data from nonneural information (New HOD Policy); and be it further

RESOLVED, that our AMA oppose any efforts to broaden the consensus medical definition of neural data to include data inferred from nonneural information gathered by biosensors (including biometric devices), as this is a distinct category of data with its own independent qualities and regulatory needs. (New HOD Policy)

Fiscal Note: Minimal – less than $1,000

Received: 4/22/25

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## RELEVANT AMA POLICY

### The Next Transformative Project: In Support of the BRAIN Initiative H-460.904

Our AMA: (1) supports the scientific and medical objectives of the Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative of mapping the human brain to better understand normal and disease process; (2) encourages appropriate scientific, medical and governmental organizations to participate in and support advancement in understanding the human brain in conjunction with the BRAIN Initiative; and (3) supports the continued Congressional allocation of funds for the BRAIN Initiative, thus providing for research and innovation in technologies that will advance knowledge of neurologic function and disease. Citation: (Res. 522, A-13; Modified: Res. 514, A-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 504
(A-25)

Introduced by: Georgia, American College of Rheumatology

Subject: Physician Performed Microscopy Designation for Synovial Fluid Crystal Exam: Modify the Clinical Laboratory Amendment of 1988

Referred to: Reference Committee E

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Whereas, there are certain microscopy tests that a physician may perform under CLIA regulations that are designated as Physician Performed Microscopy Procedures (PPMP); and

Whereas, designation as a PPMP applies to specimens subject to loss of specimen integrity, such as may occur with analysis of very small fluid volumes or the very tip of a needle used to probe a tophaceous deposit; and

Whereas, designation as a PPMP applies to specimens tested during a patient visit to allow rapid definitive diagnosis, as is true for synovial fluid crystal analysis; and

Whereas, designation as a PPMP applies to specimens that require limited specimen handling/processing, as applies to synovial fluid crystal analysis; and

Whereas, designation as a PPMP applies to tests for which commercial control materials are not available, as applies to crystal analysis; and

Whereas, designation as a PPMP has bene used for specimens such as certain wet mount microscopic procedures that are similar to synovial fluid crystal analysis; and

Whereas, synovial fluid crystal analysis is part of the specialized training required for rheumatologists and is included in the standard curriculum of rheumatology training programs and selected other training programs; therefore be it

RESOLVED, that our American Medical Association adopt the position that the CLIA Laboratory Amendment of 1988 should be modified to categorize synovial fluid crystal analysis as a permitted PPMP, to be performed by appropriately trained physicians. (New HOD Policy)

Fiscal Note: Minimal – less than $1,000

Received: 4/22/25

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 505
(A-25)

Introduced by: Indiana

Subject: Mandating Properly Fitting Lead Aprons in Hospitals

Referred to: Reference Committee E

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Whereas, health care workers are the largest occupational group exposed to radiation in the world and medical specialties like radiology, nuclear medicine, and surgery that use interventional fluoroscopy are ranked among the highest risk cohorts, consisting of 48% of occupational radiation exposure in the U.S. alone; and

Whereas, ionizing radiation, which is emitted during fluoroscopy procedures, increases cancer risk in a dose-dependent manner, specifically cancers of the breast, bladder, colon, liver, lung, esophagus, and ovaries; and

Whereas, female orthopedic surgeons have a 189% higher risk of all cancers and a four times higher risk of breast cancer as compared to the general population; and

Whereas, lead aprons are mandatory for medical staff during any procedure that emits ionizing radiation and are designed to protect tissues susceptible to oncogenic DNA damage, including the thyroid gland, chest, abdomen, and pelvis; and

Whereas, time spent performing procedures, including fluoroscopy, is longer earlier in medical training; and

Whereas, up to 72% of hospitals do not carry an appropriate range or lead apron sizes at the facility, requiring medical students and residents to borrow aprons from other staff members; and

Whereas, ill-fitting lead aprons, either too large or too small, fail to adequately cover the outer upper quadrant of the breast, where approximately 50% of breast cancers occur, and have been attributed to the increased prevalence of breast cancer in female orthopedic surgeons; and

Whereas, routine examination of lead aprons includes verifying adequate lead thickness, but does not involve evaluating whether it effectively covers the intended parts of the body; and

Whereas, the fit of a lead apron has been shown to be more important than lead thickness in protecting against radiation damage; and

Whereas, the lead apron should extend from the neck down to within 10 centimeters above the knees in the front and also cover the sides from the shoulders to below the buttocks; and

Whereas, in the United States there have been limited investigations regarding the availability of lead aprons in hospitals, but a study in Ireland found a lack of extra small and extra large aprons at radiological facilities; and

Whereas, lead aprons are relatively inexpensive, starting at $200 per apron, so it would not pose a significant financial burden on hospitals to ensure a range of sizes in stock for rotating staff members; therefore be it

RESOLVED, that our American Medical Association collaborate with relevant stakeholders to ensure:

(1) Adequate stocking of diverse lead apron sizes for all radiation-exposed personnel and medical trainees, and

(2) Consistent implementation of evidence-based radiation safety principles to keep exposure as low as reasonably achievable in accordance with specialty society guidelines, in order to promote optimal protection practices. (Directive to Take Action)

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

Received: 4/16/25

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 506
(A-25)

Introduced by: LGBTQ+ Section

Subject: Opposing the use of Harm Reduction Items as Evidence of Commercial Sex Work

Referred to: Reference Committee E

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Whereas, the selling of sex is illegal in 49 states, and sentencing is decided at the state level; and[1,2]; and

Whereas, the selling of sex may be punishable with fines, arrests, jail time, criminal records, and deportation[3]; and

Whereas, the number of arrests for prostitution is positively associated with sexually transmitted infection (STI) rates[4]; and

Whereas, sex workers are disproportionately affected by STIs[5]; and

Whereas, condom usage is the most effective contraceptive in preventing STIs and HIV besides abstinence[6,7]; and

Whereas, studies demonstrate that sex workers are discouraged to use condoms and STI protection by their clientele and are often disempowered to protect their bodily autonomy in this way, putting themselves at even greater risk for HIV and other STIs[8]; and

Whereas, the enactment of France's law no. 2016-444, intended to combat the commercial sex work system and disenfranchise sex workers, has been associated with a significant deterioration in the living and working conditions of sex workers, as evidenced by a qualitative study revealing that 38% of sex workers find it increasingly difficult to demand condom use, alongside a worrying decline in overall condom usage and increased challenges in maintaining HIV treatment due to reduced client numbers and diminished negotiating power[9]; and

Whereas, sex workers in New York, California, and other US and international jurisdictions have historically been punished for carrying condoms as they were used as evidence of illegal commercial sex work[10]; and

Whereas, anecdotes from sex workers among cities including New York, Washington, DC, Los Angeles, and San Francisco have expressed fear in carrying condoms due to police harassment and criminalization with worrying fears of vulnerability to STIs among marginalized groups including sex workers, transgender women, and lesbian, gay, bisexual, and transgender (LGBT)[10]; and

Whereas, reports have come out of California of sex workers being harassed by police for carrying condoms, lube, and PrEP, and those items being used by police as increased suspicion of commercial sex work, opening these individuals up to invasive lines of questioning[11]; and

Whereas, California passed a law prohibiting the use of condoms as evidence of sex work in 2019[12]; and

Whereas, the American Medical Association similarly advocates for the protection of those carrying and disseminating drug paraphernalia and harm reduction materials, such as needles, from prosecution on drug possession related charges[13]; and

Whereas, the protection of sex workers' ability to use and carry condoms can protect them from multiple abuses, such as in New Zealand where the Prostitution Reform Act has empowered sex workers by legally protecting their right to safer sex practices, as demonstrated by the prosecution of individuals who violate these rights, including a landmark case where a sex worker successfully pursued criminal charges against a client for "stealthing"—the non-consensual removal of a condom during sex—resulting in a conviction and prison sentence for rape[14,15]; therefore be it

RESOLVED, that our American Medical Association supports the availability and access to harm reduction tools for sex workers to protect their health and well-being; and be it further (New HOD Policy); and be it further

RESOLVED, that our AMA opposes the use of harm reduction tools as evidence in the prosecution of sex workers. (New HOD Policy)

Fiscal Note: Minimal – less than $1,000

Received: 4/21/25

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**RELEVANT AMA POLICY**

**Improving the Health and Safety of Individuals Who Offer Sex in Return for Money, Goods or Other Considerations H-65.948**

1. Our American Medical Association recognizes the adverse health outcomes of criminalizing individuals who offer sex in return for money, goods or other considerations.
2. Our AMA:
    a. supports legislation that decriminalizes individuals who offer sex in return for money, goods, or other considerations.
    b. opposes legislation that decriminalizes the purchase of sex services, as well as ownership and operation of brothels and other entities that provide such services.
    c. supports the expungement of criminal records of those previously convicted of sex work, including **trafficking** survivors.
3. Our AMA supports research on the long-term health, including mental health, impacts of decriminalization of the sex trade.

**Syringe and Needle Exchange Programs H-95.958**
Our AMA: (1) encourages all communities to establish needle exchange programs and physicians to refer their patients to such programs; (2) will initiate and support legislation providing funding for needle exchange programs for injecting drug users; and (3) strongly encourages state medical associations to initiate state legislation modifying drug paraphernalia laws so that injection drug users can purchase and possess needles and syringes without a prescription and needle exchange

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 507
(A-25)

Introduced by: Mississippi

Subject: Clinical and Public Safety Implications of AI-Generated Content and Symbolic Compliance Infrastructure

Referred to: Reference Committee E

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Whereas, artificial intelligence (AI) systems—including large language models (LLMs) and generative platforms—are increasingly deployed in clinical decision support, patient communications, education, documentation, and public health messaging; and

Whereas, AI-generated outputs may be indistinguishable from human content, and failure to visibly identify, watermark, or attribute AI authorship can lead to patient confusion, medical misinformation, reduced trust in clinical encounters, or misinterpretation of responsibility for medical decisions; and

Whereas, symbolic safety mechanisms—such as runtime policy enforcement, fallback systems under uncertainty, mirroring control, pediatric safety filters, authorship attribution, and verifiable audit trails—are emerging as critical components for ensuring that AI-generated content remains safe, ethical, age/context-appropriate, and compliant with regulatory and clinical standards; and

Whereas, the integration of such symbolic compliance infrastructure has been identified by regulatory and academic bodies as a necessary step toward mitigating AI-related harm, particularly in public-facing health applications and among vulnerable populations; and

Whereas, existing American Medical Association policy supports the responsible deployment of AI in medicine, including requirements for transparency, explainability, and physician oversight (H-480.940, H-480.931), but does not yet address runtime symbolic safety infrastructure or the need for consistent authorship enforcement, pediatric safeguards, or fallback systems; therefore be it

RESOLVED, that our American Medical Association recognize symbolic safety mechanisms—including watermarking, authorship attribution, pediatric safety filtering, public safety modes, mirroring control, fallback logic, and symbolic audit trails—as critical infrastructure components for the safe use of AI-generated content in clinical and public health settings (New HOD Policy); and be it further

RESOLVED, that our AMA request that the Council on Science and Public Health (CSAPH) prepare a report evaluating the clinical, scientific, and public health implications of symbolic safety infrastructure for AI-generated content, including its role in protecting patient trust, minimizing medical misinformation, ensuring age-appropriate communication, and preserving accountability in health-related decision making (Directive to Takek Action); and be it further

RESOLVED, that our AMA advocate for public and private entities developing or deploying generative AI in healthcare, education, and public communication to include symbolic safety

features such as authorship attribution, pediatric safeguards, fallback systems, and traceability mechanisms to ensure ethical and regulatory alignment across all deployment contexts. (Directive to Take Action)

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

Received: 4/21/25

**RELEVANT AMA POLICY**

**H-480.940 Augmented Intelligence in Health Care**
As a leader in American medicine, our American Medical Association has a unique opportunity to ensure that the evolution of augmented intelligence (AI) in medicine benefits patients, physicians, and the health care community.
To that end our AMA will seek to:
1. Leverage its ongoing engagement in digital health and other priority areas for improving patient outcomes and physicians' professional satisfaction to help set priorities for health care AI.
2. Identify opportunities to integrate the perspective of practicing physicians into the development, design, validation, and implementation of health care AI.
3. Promote development of thoughtfully designed, high-quality, clinically validated health care AI that:
a. is designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team;
b. is transparent;
c. conforms to leading standards for reproducibility;
d. identifies and takes steps to address bias and avoids introducing or exacerbating health care disparities including when testing or deploying new AI tools on vulnerable populations; and
e. safeguards patients' and other individuals' privacy interests and preserves the security and integrity of personal information.
4. Encourage education for patients, physicians, medical students, other health care professionals, and health administrators to promote greater understanding of the promise and limitations of health care AI.
5. Explore the legal implications of health care AI, such as issues of liability or intellectual property, and advocate for appropriate professional and governmental oversight for safe, effective, and equitable use of and access to health care AI.

BOT Rep. 41, A-18 Reaffirmed: CMS Rep. 07, A-24

**H.480.931 Assessing the Intersection Between AI and Health Care**
1. General Governance
    a. Health care AI must be designed, developed, and deployed in a manner which is ethical, equitable, responsible, accurate, transparent, and evidence-based.
    b. Use of AI in health care delivery requires clear national governance policies to regulate its adoption and utilization, ensuring patient safety, and mitigating inequities. Development of national governance policies should include interdepartmental and interagency collaboration.
    c. Compliance with national governance policies is necessary to develop AI in an ethical and responsible manner to ensure patient safety, quality, and continued access to care. Voluntary agreements or voluntary compliance is not sufficient.
    d. AI systems should be developed and evaluated with a specific focus on mitigating bias and promoting health equity, ensuring that the deployment of these technologies does not exacerbate existing disparities in health care access, treatment, or outcomes.
    e. Health care AI requires a risk-based approach where the level of scrutiny, validation, and oversight should be proportionate to the overall potential of disparate harm and consequences the AI system might introduc [See also Augmented Intelligence in Health Care H-480.939 at (1)]

f. AI risk management should minimize potential negative impacts of health care AI systems while providing opportunities to maximize positive impacts.
g. Clinical decisions influenced by AI must be made with specified qualified human intervention points during the decision-making process. A qualified human is defined as a licensed physician with the necessary qualifications and training to independently provide the same medical service without the aid of AI. As the potential for patient harm increases, the point in time when a physician should utilize their clinical judgment to interpret or act on an AI recommendation should occur earlier in the care plan. With few exceptions, there generally should be a qualified human in the loop when it comes to medical decision making capable of intervening or overriding the output of an AI model.
h. Health care practices and institutions should not utilize AI systems or technologies that introduce overall or disparate risk that is beyond their capabilities to mitigate. Implementation and utilization of AI should avoid exacerbating clinician burden and should be designed and deployed in harmony with the clinical workflow and, in institutional settings, consistent with AMA Policy H-225.940 - Augmented Intelligence and Organized Medical Staff.
i. Medical specialty societies, clinical experts, and informaticists are best positioned and should identify the most appropriate uses of AI-enabled technologies relevant to their clinical expertise and set the standards for AI use in their specific domain. [See Augmented Intelligence in Health Care H-480.940 at (2)]

2. When to Disclose: Transparency in Use of Augmented Intelligence-Enabled Systems and Technologies That Impact Medical Decision Making at the Point of Care
    a. Decisions regarding transparency and disclosure of the use of AI should be based upon a risk- and impact-based approach that considers the unique circumstance of AI and its use case. The need for transparency and disclosure is greater where the performance of an AI-enabled technology has a greater risk of causing harm to a patient.
        i. AI disclosure should align and meet ethical standards or norms.
        ii. Transparency requirements should be designed to meet the needs of the end users. Documentation and disclosure should enhance patient and physician knowledge without increasing administrative burden.
        iii. When AI is used in a manner which impacts access to care or impacts medical decision making at the point of care, that use of AI should be disclosed and documented to both physicians and/or patients in a culturally and linguistically appropriate manner. The opportunity for a patient or their caregiver to request additional review from a licensed clinician should be made available upon request.
        iv. When AI is used in a manner which directly impacts patient care, access to care, medical decision making, or the medical record, that use of AI should be documented in the medical record.
    b. AI tools or systems cannot augment, create, or otherwise generate records, communications, or other content on behalf of a physician without that physician's consent and final review.
    c. When AI or other algorithmic-based systems or programs are utilized in ways that impact patient access to care, such as by payors to make claims determinations or set coverage limitations, use of those systems or programs must be disclosed to impacted parties.
    d. The use of AI-enabled technologies by hospitals, health systems, physician practices, or other entities, where patients engage directly with AI, should be clearly disclosed to patients at the beginning of the encounter or interaction with the AI-enabled technology. Where patient-facing content is generated by AI, the use of AI in generating that content should be disclosed or otherwise noted within the content.
3. What to Disclose: Required Disclosures by Health Care Augmented Intelligence-Enabled Systems and Technologies
    a. When AI-enabled systems and technologies are utilized in health care, the following information should be disclosed by the AI developer to allow the purchaser and/or user (physician) to appropriately evaluate the system or technology prior to purchase or utilization:
        i. Regulatory approval status.

ii. Applicable consensus standards and clinical guidelines utilized in design, development, deployment, and continued use of the technology.
iii. Clear description of problem formulation and intended use accompanied by clear and detailed instructions for use.
iv. Intended population and intended practice setting.
v. Clear description of any limitations or risks for use, including possible disparate impact.
vi. Description of how impacted populations were engaged during the AI lifecycle.
vii. Detailed information regarding data used to train the model:
    1. Data provenance.
    2. Data size and completeness.
    3. Data timeframes.
    4. Data diversity.
    5. Data labeling accuracy.
viii. Validation Data/Information and evidence of:
    1. Clinical expert validation in intended population and practice setting and intended clinical outcomes.
    2. Constraint to evidence-based outcomes and mitigation of "hallucination"/"confabulation" or other output error.
    3. Algorithmic validation.
    4. External validation processes for ongoing evaluation of the model performance, e.g., accounting for AI model drift and degradation.
    5. Comprehensiveness of data and steps taken to mitigate biased outcomes.
    6. Other relevant performance characteristics, including but not limited to performance characteristics at peer institutions/similar practice settings.
    7. Post-market surveillance activities aimed at ensuring continued safety, performance, and equity.
ix. Data Use Policy:
    1. Privacy.
    2. Security.
    3. Special considerations for protected populations or groups put at increased risk.
x. Information regarding maintenance of the algorithm, including any use of active patient data for ongoing training.
xi. Disclosures regarding the composition of design and development team, including diversity and conflicts of interest, and points of physician involvement and review.

b. Purchasers and/or users (physicians) should carefully consider whether or not to engage with AI-enabled health care technologies if this information is not disclosed by the developer. As the risk of AI being incorrect increases risks to patients (such as with clinical applications of AI that impact medical decision making), disclosure of this information becomes increasingly important. [See also Augmented Intelligence in Health Care H-480.939]

4. Generative Augmented Intelligence
    a. Generative AI should: (a) only be used where appropriate policies are in place within the practice or other health care organization to govern its use and help mitigate associated risks; and (b) follow applicable state and federal laws and regulations (e.g., HIPAA-compliant Business Associate Agreement).
    b. Appropriate governance policies should be developed by health care organizations and account for and mitigate risks of:
        i. Incorrect or falsified responses; lack of ability to readily verify the accuracy of responses or the sources used to generate the response.
        ii. Training data set limitations that could result in responses that are out of date or otherwise incomplete or inaccurate for all patients or specific populations.
        iii. Lack of regulatory or clinical oversight to ensure performance of the tool.

iv. Bias, discrimination, promotion of stereotypes, and disparate impacts on access or outcomes.
v. Data privacy.
vi. Cybersecurity.
vii. Physician liability associated with the use of generative AI tools.

c. Health care organizations should work with their AI and other health information technology (health IT) system developers to implement rigorous data validation and verification protocols to ensure that only accurate, comprehensive, and bias managed datasets inform generative AI models, thereby safeguarding equitable patient care and medical outcomes. [See Augmented Intelligence in Health Care H-480.940 at (3)(d)]
d. Use of generative AI should incorporate physician and staff education about the appropriate use, risks, and benefits of engaging with generative AI. Additionally, physicians and healthcare organizations should engage with generative AI tools only when adequate information regarding the product is provided to physicians and other users by the developers of those tools.
e. Clinicians should be aware of the risks of patients engaging with generative AI products that produce inaccurate or harmful medical information (g., patients asking chatbots about symptoms) and should be prepared to counsel patients on the limitations of AI-driven medical advice.

5. Physician Liability for Use of Augmented Intelligence-Enabled Technologies
    a. Current AMA policy states that liability and incentives should be aligned so that the individual(s) or entity(ies) best positioned to know the AI system risks and best positioned to avert or mitigate harm do so through design, development, validation, and implementation. [See Augmented Intelligence in Health Care H-480.939]
        i. Where a mandated use of AI systems prevents mitigation of risk and harm, the individual or entity issuing the mandate must be assigned all applicable liability.
        ii. Developers of autonomous AI systems with clinical applications (screening, diagnosis, treatment) are in the best position to manage issues of liability arising directly from system failure or misdiagnosis and must accept this liability with measures such as maintaining appropriate medical liability insurance and in their agreements with users.
        iii. Health care AI systems that are subject to non-disclosure agreements concerning flaws, malfunctions, or patient harm (referred to as gag clauses) must not be covered or paid and the party initiating or enforcing the gag clause assumes liability for any harm.
    b. When physicians do not know or have reason to know that there are concerns about the quality and safety of an AI-enabled technology, they should not be held liable for the performance of the technology in question.
    c. Liability protections for physicians using AI-enabled technologies should align with both current and future AMA medical liability reform policies.

6. Data Privacy and Augmented Intelligence
    a. Entity Responsibility:
        i. Entities, e.g., AI developers, should make information available about the intended use of generative AI in health care and identify the purpose of its use. Individuals should know how their data will be used or reused, and the potential risks and benefits.
        ii. Individuals should have the right to opt-out, update, or request deletion of their data from generative AI tools. These rights should encompass AI training data and disclosure to other users of the tool.
        iii. Generative AI tools should not reverse engineer, reconstruct, or reidentify an individual's originally identifiable data or use identifiable data for nonpermitted uses, e.g., when data are permitted to conduct quality and safety evaluations. Preventive measures should include both legal frameworks and data model protections, e.g., secure enclaves, federated learning, and differential privacy.
    b. User Education:

i. Users should be provided with training specifically on generative AI. Education should address:
    1. Legal, ethical, and equity considerations.
    2. Risks such as data breaches and re-identification.
    3. Potential pitfalls of inputting sensitive and personal data.
    4. The importance of transparency with patients regarding the use of generative AI and their data.

[See H-480.940, Augmented Intelligence in Health Care, at (4) and (5)]

7. Augmented Intelligence Cybersecurity
    a. AI systems must have strong protections against input manipulation and malicious attacks.
    b. Entities developing or deploying health care AI should regularly monitor for anomalies or performance deviations, comparing AI outputs against known and normal behavior.
    c. Independent of an entity's legal responsibility to notify a health care provider or organization of a data breach, that entity should also act diligently in identifying and notifying the individuals themselves of breaches that impact their personal information.
    d. Users should be provided education on AI cybersecurity fundamentals, including specific cybersecurity risks that AI systems can face, evolving tactics of AI cyber attackers, and the user's role in mitigating threats and reporting suspicious AI behavior or outputs.

8. Mitigating Misinformation in AI-Enabled Technologies
    a. AI developers should ensure transparency and accountability by disclosing how their models are trained and the sources of their training dat Clear disclosures are necessary to build trust in the accuracy and reliability of the information produced by AI systems.
    b. Algorithms should be developed to detect and flag potentially false and misleading content before it is widely disseminated.
    c. Developers of AI should have mechanisms in place to allow for reporting of mis- and disinformation generated or propagated by AI-enabled systems.
    d. Developers of AI systems should be guided by policies that emphasize rigorous validation and accountability for the content their tools generate, and, consistent with AMA Policy H-480.939(7), are in the best position to manage issues of liability arising directly from system failure or misdiagnosis and must accept this liability with measures such as maintaining appropriate medical liability insurance and in their agreements with users.
    e. Academic publications and journals should establish clear guidelines to regulate the use of AI in manuscript submissions. These guidelines should include requiring the disclosure that AI was used in research methods and data collection, requiring the exclusion of AI systems as authors, and should outline the responsibility of the authors to validate the veracity of any referenced content generated by AI.
    f. Education programs are needed to enhance digital literacy, helping individuals critically assess the information they encounter online, particularly in the medical field where mis- and disinformation can have severe consequences.

9. Payor Use of Augmented Intelligence and Automated Decision-Making Systems
    a. Use of automated decision-making systems that determine coverage limits, make claim determinations, and engage in benefit design should be publicly reported, based on easily accessible evidence-based clinical guidelines (as opposed to proprietary payor criteria), and disclosed to both patients and their physician in a way that is easy to understand.
    b. Payors should only use automated decision-making systems to improve or enhance efficiencies in coverage and payment automation, facilitate administrative simplification, and reduce workflow burdens. Automated decision-making systems should never create or exacerbate overall or disparate access barriers to needed benefits by increasing denials, coverage limitations, or limiting benefit offerings. Use of automated decision-making systems should not replace the individualized assessment of a patient's specific

medical and social circumstances and payors' use of such systems should allow for flexibility to override automated decisions. Payors should always make determinations based on particular patient care needs and not base decisions on algorithms developed on "similar" or "like" patients.

c. Payors using automated decision-making systems should disclose information about any algorithm training and reference data, including where data were sourced and attributes about individuals contained within the training data set (e.g., age, race, gender). Payors should provide clear evidence that their systems do not discriminate, increase inequities, and that protections are in place to mitigate bias.
d. Payors using automated decision-making systems should identify and cite peer-reviewed studies assessing the system's accuracy measured against the outcomes of patients and the validity of the system's predictions.
e. Any automated decision-making system recommendation that indicates limitations or denials of care, at both the initial review and appeal levels, should be automatically referred for review to a physician (a) possessing a current and valid non-restricted license to practice medicine in the state in which the proposed services would be provided if authorized and (b) be of the same specialty as the physician who typically manages the medical condition or disease or provides the health care service involved in the request prior to issuance of any final determination. Prior to issuing an adverse determination, the treating physician must have the opportunity to discuss the medical necessity of the care directly with the physician who will be responsible for determining if the care is authorized.
f. Individuals impacted by a payor's automated decision-making system, including patients and their physicians, must have access to all relevant information (including the coverage criteria, results that led to the coverage determination, and clinical guidelines used).
g. Payors using automated decision-making systems should be required to engage in regular system audits to ensure use of the system is not increasing overall or disparate claims denials or coverage limitations, or otherwise decreasing access to care. Payors using automated decision-making systems should make statistics regarding systems' approval, denial, and appeal rates available on their website (or another publicly available website) in a readily accessible format with patient population demographics to report and contextualize equity implications of automated decisions. Insurance regulators should consider requiring reporting of payor use of automated decision-making systems so that they can be monitored for negative and disparate impacts on access to care. Payor use of automated decision-making systems must conform to all relevant state and federal laws.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution 508
(A-25)

Introduced by: Medical Student Section

Subject: Standardizing Safety Requirements for Traditional and Rideshare-Based Non-Emergency Medical Transportation

Referred to: Reference Committee E

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Whereas, each year, approximately 6 million Americans delay medical care due to lack of transportation, and transportation barriers are estimated to contribute to at least 25% of all missed clinic appointments annually[1-4]; and

Whereas, traditional Non-Emergency Medical Transportation (NEMT) programs offer Medicaid beneficiaries insured transportation to healthcare services via taxi, van, or bus, serving as a crucial resource for vulnerable populations, including individuals with disabilities, the elderly, solitary individuals, and those in rural areas[3-11]; and

Whereas, issues such as limited ride coverage, late pick-ups, and absent drivers discourage the use of traditional NEMT, but optimizing these systems can improve service quality, enhance continuity of care, and reduce emergency room visits, hospitalizations, and preventable healthcare costs for vulnerable populations[12-14]; and

Whereas, rideshare-based NEMT (RB-NEMT) programs hire rideshare drivers to use personal vehicles to provide NEMT services, broadening NEMT's accessibility, which is currently in regular use in multiple states[15,16]; and

Whereas**,** compared to traditional NEMT, RB-NEMT options increase patient attendance at health appointments, while decreasing average wait times, costs per ride, annual costs, and improving reliability and patient satisfaction rates11,[17-19]; and

Whereas**,** rideshare companies hire RB-NEMT drivers as independent contractors who typically have limited or no training in patient confidentiality or basic life support, and offered little agency to transport patients[19]; and

Whereas**,** despite established partnerships between digital transportation network companies and NEMT brokers, there is a lack of standardized trainings for drivers, as well as concerns ranging from credentialing to information sharing to medical liability[17,20]; therefore be it

RESOLVED, that our American Medical Association study and report back with recommendations on appropriate minimum safety requirements/certifications (e.g., vehicle, Basic Life Support, Health Insurance Portability and Accountability Act) for non-emergency medical transportation (NEMT) and rideshare-based non-emergency medical transportation (RB-NEMT). (Directive to Take Action)

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

Date Received: 04/10/2025

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## RELEVANT AMA POLICY

**H-130.954 Non-Emergency Patient Transportation Systems**
Our AMA: (1) supports the education of physicians, first responders, and the public about the costs associated with inappropriate use of emergency patient transportation systems; and (2) encourages the development of non-emergency patient transportation systems that are affordable to the patient, thereby ensuring cost effective and accessible health care for all patients. [Sub. Res. 812, I-93; Reaffirmed: CMS Rep. 10, A-03; Reaffirmed in lieu of Res. 101, A-12; Modified: CMS Rep. 02, I-18]

**H-90.978 Community Mobility Devices**
The AMA urges physicians, who treat patients with impaired mobility outside the home, to work with state medical associations and appropriate medical specialty societies to identify state agencies and community service organizations that provide local transportation assistance to disabled individuals, and that such information be made readily accessible to disabled patients. [CMS Rep. 10, A-97; Reaffirmed: CMS Rep. 9, A-07; Reaffirmed: CMS Rep. 01, A-17]

**H-425.993 Health Promotion and Disease Prevention**
The AMA (1) reaffirms its current policy pertaining to the health hazards of tobacco, alcohol, accidental injuries, unhealthy lifestyles, and all forms of preventable illness; (2) advocates intensified leadership to promote better health through prevention; (3) believes that preventable illness is a major deterrent to good health and accounts for a major portion of our country's total health care expenditures; (4) actively supports appropriate scientific, educational and legislative activities that have as their goals: (a) prevention of smoking and its associated health hazards; (b) avoidance of alcohol abuse, particularly that which leads to accidental injury and death; (c) reduction of death and injury from vehicular and other accidents; and (d) encouragement of healthful lifestyles and personal living habits; (5) advocates that health be considered one of the goals in transportation planning and policy development including but not limited to the establishment, expansion, and continued maintenance of affordable, accessible, barrier-free, reliable, and preferably clean-energy public transportation; and (6) strongly emphasizes the important opportunity for savings in health care expenditures through prevention. [Presidential Address, A-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: BOT Rep. 8, I-06; Reaffirmed: CSAPH Rep. 01, A-16; Modified: Res. 923, I-19]

**H-330.960 Cost of Medically Related Services and Supplies**
Our American Medical Association legislative or other appropriate department will seek a requirement that CMS and/or their contracted home health agencies, durable medical equipment suppliers, and non-emergency transportation services, provide cost estimates to physicians, to be provided along with the physician authorization form. [Res. 812, A-92; Reaffirmed by Rules & Credentials Cmt., A-96; Reaffirmation A-99Reaffirmation A-04; Reaffirmation A-08; Reaffirmed: BOT Rep. 14, A-13; Reaffirmed: BOT Rep. 09, A-23]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 509
(A-25)

Introduced by: Medical Student Section

Subject: Allergen Labeling for Spices and Herbs

Referred to: Reference Committee E

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Whereas, food allergies affect an estimated 33 million Americans, posing significant risks such as severe reactions, diminished quality of life, and substantial economic costs due to medical care and avoidance measures[1-14]; and

Whereas, the U.S. Food and Drug Administration (FDA) requires food manufacturers to list ingredients and specify common allergens, with allergy labels playing a crucial role in preventing allergic reactions[1, 5-11]; and

Whereas, the FDA allows vague labeling of food seasonings as "spices and herbs," which can include a variety of components, limiting complete ingredient transparency, while manufacturers are not required to report changes in aromatic vegetable blends classified as "spices" or "herbs"[6,7,10,11]; and

Whereas, individuals with allergies may experience cross-reactivity to compounds in spices and herbs due to shared allergenic epitopes across related families, leading to reactions in foods that seem allergen-free[9,11,12]; and

Whereas, the FDA classifies aromatic vegetables like fenugreek as "spices," which can cause anaphylactic cross-reactivity in individuals with peanut allergies, a phenomenon also observed with other common allergens like tree nuts[11,13]; and

Whereas, aeroallergens like pollen can cause sensitization to food allergens, contributing to pollen-food syndrome, which includes allergic reactions to spices from the Apiaceae family[2,12,14]; and

Whereas, an estimated 1.3 million Americans are affected by spice allergies, complicating avoidance due to ambiguous labeling and cross-contamination risks, with certain Apiaceae vegetables known to cause severe anaphylactic reactions[2,9,15]; and

Whereas, under the Fair Packaging and Labeling Act, food manufacturers must provide accurate allergen information though it protects trade secrets such as spice blends, resulting in additional efforts to improve labeling transparency, through acts like the Food Allergen Labeling and Consumer Protection Act (FALCPA) and the FASTER Act[10,16-22]; and

Whereas, clearer labeling would enhance diagnostic accuracy for physicians and help individuals with spice allergies avoid accidental exposure, thereby improving their ability to make informed food choices[9-11,15,20,23;] therefore be it

RESOLVED, that our American Medical Association support requirements for transparent disclosure of individual ingredients in aggregate categories, such as “spices and herbs,” and regular U.S. Food and Drug Administration (FDA) evaluation of labeling exemptions. (New HOD Policy)

Fiscal Note: Minimal – less than $1,000

Date Received: 4/17/25

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## RELEVANT AMA POLICY

**H-150.924 Allergen Labeling on Food Packaging**
Our AMA encourages food manufacturers to pursue more obvious packaging distinctions between products that contain the most common food allergens identified in the Food Allergen Labeling and Consumer Protection Act and products that do not contain these allergens. [Res. 918, I-18]

**D-440.932 Preventing Allergic Reactions in Food Service Establishments**
Our American Medical Association will pursue federal legislation requiring restaurants and food establishments to: (1) include a notice in menus reminding customers to let the staff know of any food allergies; (2) educate their staff regarding common food allergens and the need to remind customers to inform wait staff of any allergies; and (3) identify menu items which contain any of the major food allergens identified by the FDA (in the Food Allergen Labeling and Consumer Protection Act of 2004) and which allergens the menu item contains. [Res. 416, A-15]

**H-150.948 Increasing Awareness of Nutritional Information and Ingredient Lists**
Our American Medical Association supports legislation or rules requiring restaurants, retail food establishments, **and** vending machine operators that have menu items common to multiple locations, as well as all school **and** workplace cafeterias, especially those located in health care facilities, to have available for public viewing **ingredient lists**, nutritional **information**, **and** standard **nutrition** labels for all menu items. [Sub. Res. 411, A-04; Reaffirmation A-07; Reaffirmed in lieu of Res. 413, A-09, Res. 416, A-09 and Res. 418, A-09; Modified: BOT Rep. 1, A-14; Modified: CSAPH Rep. 01, A-24]

**H-150.926 Product Date Labels**
Our AMA will support federal standardization of date labels on food products to ensure that the labels address safety concerns. [Res. 421, A-18]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 510
(A-25)

Introduced by: Medical Student Section

Subject: Improving Cybersecurity Standards for Healthcare Entities

Referred to: Reference Committee E

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Whereas, healthcare increasingly relies on electronic infrastructure in the form of Electronic Health Records (EHR) systems, telehealth platforms, implantable devices, patient monitoring devices, and billing systems[1,2]; and

Whereas, the doubling of healthcare cyberattacks from 2016 to 2021 has exposed vulnerabilities that lead to care errors, delays, increased mortality, and disproportionate harm to minority patients, exacerbated by insufficient regulations and optional industry standards[3-8]; and

Whereas, the largest healthcare cyberattack in U.S. history at Change Healthcare, which compromised one-third of all medical records, underscored the absence of multi-factor authentication (MFA), a critical security measure capable of preventing 99.9% of automated cyberattacks and significantly reducing data breaches[9-12]; and

Whereas, the lack of original equipment manufacturer (OEM) support, timely updates, and the inconsistent use of readily available security measures like disk encryption in medical devices are significant vulnerabilities that increase the risk of cyberattacks[2,14-19]; and

Whereas, solo practitioners and rural hospitals often lack resources for cybersecurity, while larger entities like independent software vendors (ISVs), independent hardware vendors (IHVs), and OEMs, such as Google and Microsoft, have the capacity to address these challenges[20–24]; and

Whereas, healthcare cybersecurity is a focus of active regulation, with agencies like the Food and Drug Administration (FDA) introducing updated device requirements, the Department of Health and Human Services (HHS) investing in initiatives, and The White House recommending minimum standards in its National Cybersecurity Strategy[25–29]; therefore be it

RESOLVED, that our American Medical Association support the establishment of minimum cybersecurity standards, including, but not limited to, the use of multi-factor authentication, timely updates, and encryption for HIPAA covered entities. (New HOD Policy)

Fiscal Note: Minimal – less than $1,000

Date Received: 4/17/25

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## RELEVANT AMA POLICY

### D-478.957 Establish a Cyber-Security Relief Fund

Our American Medical Association, through appropriate channels, advocates for a 'Cyber Security Relief Fund" to be established by Congress. Our AMA advocates that the "Cyber Security Relief Fund" be funded through contributions from health insurance companies and all payers - as a mandated

requirement by each of the payer. Our AMA advocates that the “Cyber Security Relief Fund” only be utilized for ‘uninterrupted’ payments to all providers- in a structured way, in the event of future cyber-attacks affecting payments. [Res. 235, A-24]

**H-515.950 Protecting Physicians and Other Healthcare Workers in Society**
Our American Medical Association acknowledges and will act to reduce the incidence of antagonistic actions against physicians as well as other health care workers including first responders and public health officials, outside as well as within the workplace, including physical violence, intimidating actions of word or deed, and cyber-attacks, particularly those which appear motivated simply by their identification as health care workers. [Res. 413, I-20 Reaffirmed: CSAPH Rep. 7, I-23]

**D-478.959 Ransomware Prevention and Recovery**
Our AMA will: (1) work with other stakeholders to seek legislation or regulation that supports resources to cover cyberattack prevention and recovery expenses for physician practices, hospitals, and healthcare entities to ensure continuity of optimal patient care; and (2) in collaboration with appropriate stakeholders, develop a toolkit for physician practices, hospitals, and healthcare entities to include best practices on preventing cyberattacks and a plan of action for when such an attack happens to their practice or institution; the toolkit should include guides to financial resources. [Res. 240, I-21]

**D-478.960 Ransomware and Electronic Health Records**
Our American Medical Association acknowledges that healthcare data interruptions are especially harmful due to potential physical harm to patients and calls for prosecution to the fullest extent of the law for perpetrators of ransomware and any other malware on independent physicians and their practices, healthcare organizations, or other medical entities involved in providing direct and indirect care to patients. Our AMA will: (a) advocate for federal legislation which provides for the prosecution of perpetrators of ransomware and any other malware on any and all healthcare entities, involved in direct and indirect patient care, to the fullest extent of the law; (b) encourage health care facilities and integrated networks that are under threat of ransomware attacks to upgrade their cybersecurity and to back up data in a robust and timely fashion; (c) advocate that the security of protected healthcare information be considered as an integral part of national cybersecurity protection; and (d) seek inclusion of federal cybersecurity resources allocated to physician practices, hospitals, and health care entities sufficient to protect the security of the patients they serve, as part of infrastructure legislation. [Res. 210, A-21 Reaffirmation: Res. 241, A-24]

**3.3.3 Breach of Security in Electronic Medical Records**
When there is reason to believe that patients’ confidentiality has been compromised by a breach of the electronic medical record, physicians should: (a) Ensure that patients are promptly informed about the breach and potential for harm, either by disclosing directly (when the physician has administrative responsibility for the EMR), participating in efforts by the practice or health care institution to disclose, or ensuring that the practice or institution takes appropriate action to disclose. (b) Follow all applicable state and federal laws regarding disclosure. [Issued: 2016]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 511
(A-25)

Introduced by: Medical Student Section

Subject: Increased Transparency Among Psychotropic Drug Administration in Prisons

Referred to: Reference Committee E

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Whereas, the prevalence of mental health disorders among incarcerated individuals is disproportionately higher than the general population (22.8% in 2021), with 64% of jail inmates, 54% of state prisoners, and 45% of federal prisoners reporting mental health concerns, 37% of federal prisoners and 44% of jail inmates having a prior mental health diagnosis, and 14% of federal prisoners and 26% of jail inmates having serious psychological distress;[1-3,10] and

Whereas, psychotropic drugs, such as antipsychotics, antidepressants, mood stabilizers, and tranquilizers have significant adverse side effects, suggesting the need for close monitoring if these drugs are used;[4,5] and

Whereas, these medications are frequently used on incarcerated patients, yet prisons are known to have staffing deficiencies in their medical units, often resulting in fatal delays to accessing care;[4,6,7] and

Whereas, inmates can be involuntarily medicated if the state has clear, cogent, and convincing evidence that it is in the state's interest at that time, such as for the safety of the inmate or others, bypassing the assessment for capacity and leading to abundant opportunities for abuse and control of incarcerated populations;[4,8] and

Whereas, many state and federal prisons currently lack transparency regarding their policies and protocols for psychotropic drug administration, including, but not limited to, administration, duration, side effects, and drug(s) of choice;[4,9] and

Whereas, there are limited data surrounding the incarcerated patients' experience with mental illness and treatment, as well as side effects and complications of use of psychotropic drugs in incarcerated populations due to the regular exclusion of this population from large scale population health surveys;[6] and

Whereas, the limited access to these data impedes research and advocacy efforts for this patient population, who are at high risk of adverse health outcomes; therefore be it

RESOLVED, that our American Medical Association study issues surrounding the use of psychotropic medications in the carceral system, including inconsistencies in dosage, frequency, duration, allowed formularies, side effects, and oversight by a psychiatrist or another physician with expertise in mental illness (Directive to Take Action); and be it further

RESOLVED, that our AMA support increased transparency from state and federal jails and prisons surrounding protocols pertaining to the administration of psychotropic medications, including components such as dosage, frequency, duration, allowed formularies, management

of side effects, and requirements for oversight by a psychiatrist or another physician with expertise in mental illness. (New HOD Policy)

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

Date Received: 4/21/25

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## RELEVANT AMA POLICY

**H-430.987 Medications for Opioid Use Disorder in Correctional Facilities**
Our AMA advocates for legislation, standards, policies and funding that require correctional facilities to increase access to evidence-based treatment of OUD, including initiation and continuation of medications for OUD, in conjunction with psychosocial treatment when desired by the person with OUD, in correctional facilities within the United States and that this apply to all individuals who are incarcerated, including individuals who are pregnant, postpartum, or parenting. [Res. 443, A-05; Reaffirmed: CSAPH Rep. 1, A-15; Appended: Res. 223, I-17; Modified: Res. 503, A-21]

**H-430.986 Health Care While Incarcerated**
Our AMA supports: (a) linkage of those incarcerated to community clinics upon release in order to accelerate access to comprehensive health care, including mental health and substance use disorder services, and improve health outcomes among this vulnerable patient population, as well as adequate funding; (b) the collaboration of correctional health workers and community health care providers for those transitioning from a correctional institution to the community; (c) the provision of longitudinal care from state supported social workers, to perform foundational check-ins that not only assess mental health but also develop lifestyle plans with newly released people; and (d) collaboration with community-based organizations and integrated models of care that support formerly incarcerated people with regard to their health care, safety, and social determinant of health needs, including employment, education, and housing. [CMS Rep. 02, I-16; Appended: Res. 417, A-19; Appended: Res. 420, A-19; Modified: Res. 216, I-19; Modified: Res. 503, A-21; Reaffirmed: Res. 229, A-21; Modified: Res. 127, A-22; Appended: Res. 244, A-23; Appended: Res. 429, A-23]

**D-430.997 Support for Health Care Services to Incarcerated Persons**
Our AMA will express its support of the National Commission on Correctional Health Care Standards that improve the quality of health care services, including mental health services, delivered to the nation's correctional facilities; [Res. 440, A-04; Amended: BOT Action in response to referred for decision Res. 602, A-00; Reaffirmation I-09; Reaffirmation A-11; Reaffirmed: CSAPH Rep. 08, A-16; Reaffirmed: CMS Rep, 02, I-16; Appended: Res. 421, A-19; Appended: Res. 426, A-19; Reaffirmed: CSAPH Rep. 06, A-23]

**H-130.932 Pharmacological Intervention for Agitated Individuals in the Out-of-Hospital Setting**
Our AMA:
1. Believes that current evidence does not support “excited delirium” or “excited delirium syndrome” as a medical diagnosis and opposes the use of the terms until a clear set of diagnostic criteria are validated.
2. Recognizes that the treatment of medical emergency conditions outside of a hospital is usually done by a subset of healthcare practitioners who are trained and have expertise as emergency medical service (EMS) practitioners. It is vital that EMS practitioners and systems are overseen by physicians who have specific experience and expertise in providing EMS medical direction.
3. Is concerned about law enforcement officer use of force accompanying “excited delirium” that leads to disproportionately high mortality among communities of color, particularly among Black men, and denounces “excited delirium” solely as a justification for the use of force by law enforcement officers.
4. Opposes the use of sedative/hypnotic and dissociative agents, including ketamine, as a pharmacological intervention for agitated individuals in the out-of-hospital setting, when done solely for a law enforcement purpose and not for a legitimate medical reason.
5. Recognizes that sedative/hypnotic and dissociative pharmacological interventions for agitated individuals used outside of a hospital setting by non-physicians have significant risks intrinsically, in the context of age, underlying medical conditions, and also related to potential drug-drug interactions with agents the individual may have taken.
6. Encourages the continued use of the necessary and effective dual-response method of communication between law enforcement and EMS to appropriately care for all patients encountered by first responders, including those patients demonstrating agitated or combative behavior.
7. Calls for comprehensive, independent analysis of law enforcement agencies to:
a. Review cases labeled as “excited delirium” to determine frequency of use of the term, including prevalence of its use by race, ethnicity, gender, age, and other demographic factors;
b. Assess the available training and guidelines used to prepare law enforcement first responders to respond to individuals with agitated or combative behavior, including de-escalation training;
c. Assess efforts to ensure adherence to approved training on an ongoing basis.
8. Calls for comprehensive, independent analysis, performed by appropriate medical and behavioral health professionals, of EMS agencies to:
a. Review the usage of ketamine and other sedative-hypnotic medications used to sedate patients with agitated or combative behavior and correlation of the tern “excited delirium” with race, ethnicity, gender, age or other demographic factors;
b. Assess whether existing training and guidelines, including continuous quality improvement processes, have been properly established by supervising EMS medical directors and behavioral health specialists, to:
i. Require appropriate monitoring of any patient who receives sedative/hypnotic and dissociative pharmacological interventions for treatment in the out-of-hospital setting;
ii. Ensure proper use of ketamine and other sedative/hypnotic and dissociative pharmacological interventions under defined protocols/guidelines after appropriate education on indications, usage and complications;
iii. Include an appropriate stepwise approach to the treatment of patients in the out-of-hospital setting, including de-escalation training, that provides safety to the patient and providers; and
c. Assess, on an ongoing basis, that personnel are conducting themselves according to guidelines and training.
9. Urges law enforcement and frontline emergency medical service personnel, who are a part of the “dual response” in emergency situations, to participate in appropriate training, overseen by EMS medical directors. The training should minimally include de-escalation techniques and the appropriate use of pharmacological intervention for agitated individuals in the out-of-hospital setting.

10. Urges medical and behavioral health specialists, not law enforcement, to serve as first responders and decision makers in medical and mental health emergencies in local communities and that administration of any pharmacological treatments in the out-of-hospital setting be done equitably, in an evidence-based, anti-racist, and stigma-free way. [CSAPH Rep. 2, A-21; Appended: BOT Action in response to referred for decision: CSAPH Rep. 2, A-21]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 512
(A-25)

Introduced by: Medical Student Section

Subject: Preventing Drug-Facilitated Sexual Assault in Drinking Establishments

Referred to: Reference Committee E

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Whereas, an estimated 1 in 5 women have experienced completed or attempted rape, and 1 in 4 men have experienced some variation of sexual violence in their lifetime, with nearly half of all sexual assaults involving alcohol consumption by the survivor, perpetrator, or both[1-3]; and

Whereas, alcohol is identified as the most commonly detected substance in drug-facilitated sexual assaults (DFSA) globally, with a significant portion of survivors reporting the use of substances such as MDMA, GHB, ketamine, methamphetamine, and Rohypnol by perpetrators[4–7]; and

Whereas, college students and young adults are highly vulnerable to drug-facilitated sexual assault (DFSA), with over 60% of incidents occurring in social settings like parties, bars, or clubs, and only 20% of all survivors reporting assaults due to fear, shame, or impaired memory, underscoring the urgent need for targeted preventive interventions[8-11]; and

Whereas, due to the prolonged time frame between an assault and its reporting and the rapid clearance of many of these substances from the blood and urine, testing of drink samples has been found to grant investigators much-needed insight[12]; and

Whereas**,** various drug detection devices, such as GHB and ketamine test kits, Drink Check Wristbands, and Personal Drink IDs, have been developed and sold at relatively low costs for the express purpose of preventing DFSA[13–18]; and

Whereas, cities such as San Diego have recognized the importance of preventing DFSA by requiring alcohol-selling establishments to have drug detection devices available under Assembly Bill No. 1013, reflecting a growing trend in policy aimed at proactive prevention rather than reactive response[19]; and

Whereas, the American Medical Association has existing policy addressing sexual assault prevention on college campuses and education on sexual assault prevention and violence but lacks policy supporting efforts to prevent DFSA; therefore it be

RESOLVED, that our American Medical Association support federal, state, and local efforts to prevent drug-facilitated sexual assault, including provision of drug detection equipment in establishments that sell alcohol and through public education campaigns. (New HOD Policy)

Fiscal Note: Minimal – less than $1,000

Date Received: 4/21/25

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## RELEVANT AMA Policy

### H-515.956 Addressing Sexual Assault on College Campuses

Our AMA: (1) supports universities' implementation of evidence-driven sexual assault prevention programs that specifically address the needs of college students and the unique challenges of the collegiate setting; (2) will work with relevant stakeholders to address the issues of rape, sexual abuse, and physical abuse on college campuses; and (2) will strongly express our concerns about the problems of rape, sexual abuse, and physical abuse on college campuses. [Res. 402, A-16; Appended: Res. 424, A-18]

**Preventing, Identifying and Treating Violence and Abuse 8.10**
All patients may be at risk for interpersonal violence and abuse, which may adversely affect their health or ability to adhere to medical recommendations. In light of their obligation to promote the well-being of patients, physicians have an ethical obligation to take appropriate action to avert the harms caused by violence and abuse.
To protect patients' well-being, physicians individually should:
(a) Become familiar with:
(i) how to detect violence or abuse, including cultural variations in response to abuse;
(ii) community and health resources available to abused or vulnerable persons;
(iii) public health measures that are effective in preventing violence and abuse;
(iv) legal requirements for reporting violence or abuse.
(b) Consider abuse as a possible factor in the presentation of medical complaints.
(c) Routinely inquire about physical, sexual, and psychological abuse as part of the medical history.
(d) Not allow diagnosis or treatment to be influenced by misconceptions about abuse, including beliefs that abuse is rare, does not occur in "normal" families, is a private matter best resolved without outside interference, or is caused by victims' own actions.
(e) Treat the immediate symptoms and sequelae of violence and abuse and provide ongoing care for patients to address long-term consequences that may arise from being exposed to violence and abuse.
(f) Discuss any suspicion of abuse sensitively with the patient, whether or not reporting is legally mandated, and direct the patient to appropriate community resources.
(g) Report suspected violence and abuse in keeping with applicable requirements. Before doing so, physicians should:
(i) inform patients about requirements to report;
(ii) obtain the patient's informed consent when reporting is not required by law. Exceptions can be made if a physician reasonably believes that a patient's refusal to authorize reporting is coerced and therefore does not constitute a valid informed treatment decision.
(h) Protect patient privacy when reporting by disclosing only the minimum necessary information.
Collectively, physicians should:
(i) Advocate for comprehensive training in matters pertaining to violence and abuse across the continuum of professional education.
(j) Provide leadership in raising awareness about the need to assess and identify signs of abuse, including advocating for guidelines and policies to reduce the volume of unidentified cases and help ensure that all patients are appropriately assessed.
(k) Advocate for mechanisms to direct physicians to community or private resources that might be available to aid their patients.
(l) Support research in the prevention of violence and abuse and collaborate with public health and community organizations to reduce violence and abuse.
(m) Advocate for change in mandatory reporting laws if evidence indicates that such reporting is not in the best interests of patients.
AMA Principles of Medical Ethics: I,III Issued: 2016

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 513
(A-25)

Introduced by: Medical Student Section

Subject: Transparency on Comparative Effectiveness in Direct-to-Consumer Advertising

Referred to: Reference Committee E

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Whereas, studies show that direct-to-consumer advertising (DTCA) significantly influences patient and provider perceptions of medications, sometimes leading to overestimation of benefits and underestimation of risks, underscoring the need for more stringent regulation and accurate representation of clinical data in drug advertisements[1,3]; and

Whereas, physicians are substantially likelier to prescribe DTCA medications when requested by their patients, despite having reservations about their clinical appropriateness[2]; and

Whereas, countries such as France, Germany and Canada have assigned health technology assessment (HTA) agencies to classify drugs based on their added clinical benefit, prioritizing evidence from randomized trials that compare the new drug to an existing treatment, with studies showing a strong agreement between these agencies on assessments of comparative effectiveness, especially of ultra-expensive drugs[4-7, 8]; and

Whereas, Section 1194(e) of the Inflation Reduction Act requires the Centers for Medicare and Medicaid Services to consider comparative effectiveness in Medicare Drug Price Negotiations, a principle that should also apply to DTCA, which is not currently addressed in AMA policy H-105.988 regarding the assessment or advertisement of a drug's comparative effectiveness or added clinical benefit within its class or purpose[9]; and

Whereas, The Effective Health Care Program funds individual researchers, research centers, and academic organizations to work with the Agency for Healthcare Research and Quality (AHRQ) to produce effectiveness and comparative effectiveness research for clinicians, consumers, and policymakers[10]; and

Whereas, by presenting comparative effectiveness data clearly and with guidance from healthcare professionals, patient education materials could improve understanding and adherence to treatment plans, enhancing care quality and helping physicians tailor drug choices to individual patient needs[11-13]; therefore be it

RESOLVED, that our American Medical Association supports the designation of an appropriate government health agency, such as the Agency for Healthcare Research and Quality (AHRQ), to:

a. review data on diagnostic and treatment modalities, prioritizing evidence from randomized controlled clinical trials;

b. evaluate their comparative effectiveness when compared to existing standard of care and other benefits such as convenience, formulation, and route of administration;
c. require that any corporate advertisements for a modality include agency-approved information on comparative effectiveness. (New HOD Policy)

Fiscal Note: Minimal – less than $1,000

Date Received: 4/22/25

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## RELEVANT AMA POLICY

**H-105.988 Direct-to-Consumer Advertising (DTCA) of Prescription Drugs and Implantable Devices**
Our AMA: … 2.That until such a ban is in place, our American Medical Association 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. … 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. [BOT Rep. 38, A-99; Sub. Res. 513, A-99; Reaffirmed: CMS Rep. 9, I-99; Amended: Res. 509, I-99; Appended & Reaffirmed: Sub. Res. 503, A-01; Reaffirmed: Res. 522, A-02; Reaffirmed: Res. 914, I-02; Reaffirmed: Sub. Res. 504, A-03;

Reaffirmation A-04; Reaffirmation A-05; Modified: BOT Rep. 9, A-06; Reaffirmed in lieu of Res. 514, A-07; BOT Action in response to referred for decision: Res. 927, I-15; Modified: BOT Rep. 09, I-16; Appended: Res. 236, A-17; Reaffirmed in lieu of: Res. 223, A-17; Reaffirmed in lieu of: Res. 112, A-19; Reaffirmed in lieu of: Res. 810, I-22; Reaffirmation A-23]

**Direct-to-Consumer Advertisement of Prescription Drugs, 9.6.7**
Direct-to-consumer advertising may raise awareness about diseases and treatment and may help inform patients about the availability of new diagnostic tests, drugs, treatments, and devices. However, direct-to-consumer advertising also carries the risk of creating unrealistic expectations for patients and conflicts of interest for physicians, adversely affecting patients' health and safety, and compromising patient physician relationships.
(Issued: 2016)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 514
(A-25)

Introduced by: New England, The American Thoracic Society

Subject: Support for a Nicotine Free Generation

Referred to: Reference Committee E

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Whereas, the addictive nature of nicotine is established[1]; and

Whereas, the combustible form of nicotine delivery has serious morbidity and mortality consequences in that “smoking kills more people in this country than HIV, drug overdoses, alcohol use, motor vehicle crashes, and firearm-related injuries combined”;[2] and

Whereas, there is evidence that non-combustible forms of nicotine delivery systems have cancer-causing chemicals and precursors similar to combustible forms — “E-cigarette devices and vaping fluids demonstrably contain a series of both definite and probable oncogens including nicotine derivatives (e.g., nitrosnornicotine, nitrosamine ketone), polycyclic aromatic hydrocarbons, heavy metals (including organometal compounds) and aldehydes/other complex organic compounds. These arise both as constituents of the e-liquid (with many aldehydes and other complex organics used as flavorings) and as a result of pyrolysis/complex organic reactions in the electronic cigarette device (including unequivocal carcinogens such as formaldehyde — formed from pyrolysis of glycerol). Various studies demonstrate in vitro transforming and cytotoxic activity of these derivatives”;[3] and

Whereas, there is a concerning prevalence of noncombustible addictive nicotine delivery system use in this country by children and adolescents — 5.9% use e-cigarettes and 1.8% use addictive nicotine pouches, for a combined total of 1,600,000 children;[4] and

Whereas, every day, almost 2,500 children under 18 years of age try their first cigarette, more than 400 of them will become new, regular daily smokers, and half of them will ultimately die from their habit;[5,6] and

Whereas, cigarette smoking causes about one out of every three cancer deaths in the United States;[7] and

Whereas, the nicotine-free generation (NFG) concept is a relatively new tobacco control strategy that phases in an end to commercial nicotine use by prohibiting the sale of nicotine products to anyone born after a chosen date (e.g., January 1, 2004), while permitting those born before that date to be sold products indefinitely, thereby preventing sales to the next generation and phasing out sales slowly over time;[8] and

Whereas, in New England the Massachusetts Medical Society supported the town of Brookline, Massachusetts, by signing on to an amicus brief in SIX BROTHERS, INC. vs. TOWN OF BROOKLINE, wherein the bylaw prohibits the sales of nicotine products to anyone born on or

after January 1, 2000. The MA Supreme Judicial Court unanimously supported Brookline in its decision;[9] and

Whereas, as of April 2, 2025, the following Massachusetts cities and towns have adopted NFG policy: Brookline via by-law, Stoneham, Wakefield, Melrose, Malden, Winchester, Reading, Concord, Manchester, Chelsea, Belchertown, Needham, and Newton via city ordinance, and Pelham via resolution; and

Whereas, legislation has been filed in the Massachusetts State House and Senate, An Act *to create a nicotine free generation* (HD2372 and SD1317);[10, 11] therefore be it

RESOLVED, that our American Medical Association advocate for legislation establishing a "Nicotine Free Generation" through the prohibition on sale of addictive nicotine products to anyone born after a chosen date (Directive to Take Action); and be it further

RESOLVED, that our AMA alert its members to current opportunities to create "Nicotine Free Generation" policies through the prohibition on sale of addictive nicotine products to anyone born after a chosen date within the towns, cities, and states where they practice and live. (Directive to Take Action)

Fiscal Note: Resolve 1: Modest – between $1,000 - $5,000
Resolve 2: Minimal – less than $1,000

Date Received: 4/15/25

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**RELEVANT AMA POLICY**

**H-30.958. Ethyl Alcohol and Nicotine as Addictive Drugs.**
The AMA (1) identifies alcohol and nicotine as drugs of addiction which are gateways to the use of other drugs by young people; (2) urges all physicians to intervene as early as possible with their patients who use tobacco products and have problems related to alcohol use, so as to prevent adverse health effects and reduce the probability of long-term addition; (3) encourages physicians who treat patients with alcohol problems to be alert to the high probability of co-existing nicotine problems; and (4) reaffirms that

individuals who suffer from drug addiction in any of its manifestations are persons with a treatable disease.

**H-490.911. Smoke-Free America.**
Our AMA makes the passage of legislation for a smoke-free America, that includes all public and workplaces and includes provisions for support of smoking cessation programs, a legislative priority for the AMA until such legislation is passed.

**D-490.998. Tobacco Control and Settlement**
Our AMA: (1) will undertake action to publicize, support and implement the elements of its policies that have not been adequately addressed by the Master Settlement Agreement and other agreements, including but not limited to:

(a) A complete ban on tobacco industry promotion and advertising;
(b) Regulation of tobacco sales, including a ban on vending machines and a mandate for behind the counter sales;
(c) Tax increases on tobacco products;
(d) Protection from environmental tobacco smoke;
(e) Regulation of nicotine as a drug by the Food and Drug Administration; and
(f) Look back provisions; and

(2) will work with Congress, the Administration and other groups to achieve public health goals and accomplish the issues addressed by our AMA policies through federal and state tobacco control legislation.

**H-495.977. Banning the Sale of Tobacco Products in Pharmacies and Health Care Facilities**
Our AMA supports efforts to ban the sale of tobacco products meeting the definition of "tobacco product" under the Family Smoking Prevention and Tobacco Control Act, with the exception of medicinal nicotine products approved by the FDA, where health care is delivered or where prescriptions are filled, including retail outlets housing store-based health clinics.

**H-495.983 Tobacco Litigation Settlements**
1. Our American Medical Association strongly supports the position that all monies paid to the states in the Master Settlement Agreement and other agreements be utilized for research, education, prevention and treatment of nicotine addiction, especially in children and adolescents, and for treatment of diseases related to nicotine addiction and tobacco use.
2. Our AMA supports efforts to ensure that a substantial portion of any local, state or national tobacco litigation settlement proceeds be directed towards preventing children from using tobacco in any form, helping current tobacco users quit, and protecting nonsmokers from environmental tobacco smoke, and that any tobacco settlement funds not supplant but augment health program funding.
3. Our AMA strongly supports efforts to direct tobacco settlement monies that are not directed to other specific tobacco control activities to enhance patient access to medical services.
4. Our AMA strongly supports legislation codifying the position that all monies paid to the states through the various tobacco settlements remain with the states; and that none be reimbursed to the Federal government on the basis of each individual state's Federal Medicaid match.
5. Our AMA opposes any provision of tort reform legislation that would grant exclusion from liability or special protection to tobacco companies or tobacco products.

**H-495.986. Sales and Distribution of Tobacco Products and Electronic Nicotine Delivery Systems (ENDS) and E-cigarettes**
1. Our American Medical Association recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and will actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices, including but not limited to bans and strict restrictions on marketing to minors under the age of 21;

2. Our AMA encourages the passage of laws, ordinances and regulations that would set the minimum age for purchasing tobacco products, including electronic nicotine delivery systems (ENDS) and e-cigarettes, at 21 years, and urges strict enforcement of laws prohibiting the sale of tobacco products to minors;
3. Our AMA supports the development of model legislation regarding enforcement of laws restricting children's access to tobacco, including but not limited to attention to the following issues: (a) provision for licensure to sell tobacco and for the revocation thereof; (b) appropriate civil or criminal penalties (e.g., fines, prison terms, license revocation) to deter violation of laws restricting children's access to and possession of tobacco; (c) requirements for merchants to post notices warning minors against attempting to purchase tobacco and to obtain proof of age for would-be purchasers; (d) measures to facilitate enforcement; (e) banning out-of-package cigarette sales ("loosies"); and (f) requiring tobacco purchasers and vendors to be of legal smoking age;
4. Our AMA requests that states adequately fund the enforcement of the laws related to tobacco sales to minors;
5. Our AMA opposes the use of vending machines to distribute tobacco products and supports ordinances and legislation to ban the use of vending machines for distribution of tobacco products;
6. Our AMA seeks a ban on the production, distribution, and sale of candy products that depict or resemble tobacco products;
7. Our AMA opposes the distribution of free tobacco products by any means and supports the enactment of legislation prohibiting the disbursement of samples of tobacco and tobacco products by mail;
8. Our AMA:
    a. publicly commends (and so urges local medical societies) pharmacies and pharmacy owners who have chosen not to sell tobacco products, and asks its members to encourage patients to seek out and patronize pharmacies that do not sell tobacco products;
    b. encourages other pharmacists and pharmacy owners individually and through their professional associations to remove such products from their stores;
    c. urges the American Pharmacists Association, the National Association of Retail Druggists, and other pharmaceutical associations to adopt a position calling for their members to remove tobacco products from their stores; and
    d. encourages state medical associations to develop lists of pharmacies that have voluntarily banned the sale of tobacco for distribution to their members.
9. Our AMA opposes the sale of tobacco at any facility where health services are provided; and
10. Our AMA supports that the sale of tobacco products be restricted to tobacco specialty stores.
11. Our AMA supports measures that decrease the geographic density of tobacco retail stores, including but not limited to, preventing retailers from selling tobacco products in stores in close proximity to schools.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 515
(A-25)

Introduced by: New York

Subject: Nitrous Oxide Abuse

Referred to: Reference Committee E

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Whereas, nitrous oxide is a colorless gas used as a sedative for medical/dental procedures well known to the medical profession; and

Whereas, abuse of nitrous oxide is known to impair the body's metabolism of vitamin B12, causing combined degeneration of the spinal cord as well as peripheral neuropathies. Neuropsychiatric symptoms can include depression, anxiety, aggressive behaviors, hallucinations and delusions; and

Whereas, there has been a massive increase in the recreational use of nitrous oxide, often being sold in smoke shops marketed to teenagers; and

Whereas, as detailed in a recent article in the December 30, 2024, edition of New York Magazine called "The Next Drug Epidemic is Blue Raspberry Flavored", speaks to how the industry comes up with flavors, and clever social media campaigns but tries to dodge legal responsibility by having people sign waivers that they plan to use for culinary purposes to give whipped cream the fluffy consistency found in store-bought cans; and

Whereas, a small greedy group profits off Americans while the regulatory process of the government is slow to react. There is no meaningful federal regulation. Some states have taken action. In March 2024, Michigan passed a law making it unlawful to sell nitrous paraphernalia for recreational use. Two months later, Louisiana became the first state to ban commercial sales of the gas entirely. Other states have proposed banning smoke shops from selling nitrous entirely; therefore be it

RESOLVED, that our American Medical Association support efforts on the federal level to educate the public regarding the harmful effects of inhaled nitrous oxide use and work with local stakeholders to limit the ability to acquire nitrous oxide for inhalation purposes. (New HOD Policy)

Fiscal Note: Minimal – less than $1,000

Received: 4/22/25

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 516
(A-25)

Introduced by: Organized Medical Staff Section

Subject: Creating a Registry of Potential Side Effects of GIP & GLP-1 Medications

Referred to: Reference Committee E

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Whereas, gastric inhibitory polypeptide (GIP) and glucagon-like peptide-1 (GLP-1) medications continue to be heavily advertised and touted as some kind of miracle drug for weight loss—besides their main indication as treatment for diabetes, there are limited studies on the potential side-effects—especially those involving the senior (65 years and older) population, such as muscle loss and bone density loss; and

Whereas, the costs of these medications continue to be high and they can potentially cost the healthcare system a lot of money over the long run; and

Whereas, there are no clear guidelines of how long patients should be taking these medications, which are meant to be long-term and potentially life-long weight management medications, and whether the weight loss will be maintained if patients ever want to come off them; and

Whereas, there are no long-term studies of the potential side effects of these medications while many side effects have been seen; and

Whereas, there are no current recommendations to better safeguard patients taking these medications and patients are not required to be monitored by qualified health professionals, such as obesity specialists, endocrinologists, or gastroenterologists, while taking these medications; therefore be it

RESOLVED, that our American Medical Association support and call for a registry of GIP and GLP-1 receptor agonists' side effects, as well as potential impacts on pregnancy (Directive to Take Action).

Fiscal Note: Minimal – less than $1,000

Received: 2/28/2025

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 517
(A-25)

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|---|---|
| Introduced by: | Resident and Fellow Section, American Academy of Addiction Psychiatry, American Psychiatric Association, American Academy of Child and Adolescent Psychiatry, American Association for Geriatric Psychiatry, American Academy of Psychiatry and the Law, Academy of Consultation-Liaison Psychiatry |
| Subject: | In Support of a National Drug Checking Registry |
| Referred to: | Reference Committee E |

Whereas, recreational substance use is becoming increasingly more common, with 13.3% of respondents to a 2020 CDC survey reporting that they either started or increased substance use to help deal with stress related to COVID-19;[1] and

Whereas, recreational drugs have been found to be contaminated with adulterants at a rate up to nearly 80%;[2–4] and

Whereas, fentanyl was present in 77% of adolescent overdose deaths in 2021;[5] and

Whereas, nearly two-thirds of all overdose deaths in the United States from 2019-2020 involved synthetic opioids;[6] and

Whereas, drug checking services are point-of-care tests provided at events with high recreational drug use that can rapidly provide information to a user on the composition of the drug they intend to take;[7] and

Whereas, 94% of users of drug checking services reported they would not take a drug whose test results were unexpected;[8] and

Whereas, 32% of users of drug checking services reported that they would not take a drug if it was found to contain adulterants;[8] and

Whereas, a majority of users of drug checking services intended to share the results of the test with others;[9] and

Whereas, drug checking services can also serve as a point of contact with users of recreational drugs for other harm reduction services, and accessibility to these resources through drug checking services is overwhelmingly supported by the target market;[10] and

Whereas, availability of drug checking services does not lead to an increase in intent to use recreational drugs;[11] and

Whereas, drug checking services are supported by over 80% of the target population;[12] and

Whereas, the Department of Health and Human Services reports that efforts to provide drug checking services have been largely effective in changing intended and actual drug use behavior;[13] and

Whereas, drug-checking services in the United States today do not have an established way to communicate trends in their results with one another; and

Whereas, a network of drug-checking services across the country could be an alternative source of information to DEA seizures to help identify early trends in supply contamination and provide education on upcoming contamination concerns to users, such as the rise of new contaminants like xylazine;[14] therefore be it

RESOLVED, that our American Medical Association study the creation of a national drug-checking registry that would provide a mechanism whereby community-run drug-checking services may communicate their results. (Directive to Take Action)

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

Received: 4/21/25

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**RELEVANT AMA POLICY:**

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

2.Our AMA will: (a) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of a drug-related overdose; and (b) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for a drug-related overdose.
3. Our AMA will support the development and implementation of appropriate education programs for persons receiving treatment for a SUD or in recovery from a SUD and their friends/families that address harm reduction measures.
4. Our AMA will advocate for and encourage state and county medical societies to advocate for harm reduction policies that provide civil and criminal immunity for the use of “drug paraphernalia” designed for harm reduction from drug use, including but not limited to drug contamination testing and injection drug preparation, use, and disposal supplies. [Res. 526, A-06; Modified in lieu of Res. 503, A-12; Appended: Res. 909, I-12; Reaffirmed: BOT Rep. 22, A-16; Modified: Res. 511, A-18; Reaffirmed: Res. 235, I-18; Modified: Res. 506, I-21; Appended: Res. 513, A-22; Modified: Res. 211, I-22; Appended: Res. 221, A-23; Reaffirmation: A-23; Modified: Res. 505, A-23; Reaffirmed: BOT Rep. 18, A-24]

**Pilot Implementation of Supervised Injection Facilities H-95.925**
Our AMA supports the development and implementation of pilot supervised injection facilities (SIFs) in the United States that are designed, monitored, and evaluated to generate data to inform policymakers on the feasibility, effectiveness, and legal aspects of SIFs in reducing harms and health care costs related to injection drug use. [Res. 513, A-17; Reaffirmation: A-23]

**Harmful Drug Use in the United States - Strategies for Prevention H-95.978**
Our AMA: (1) Urges the Substance Abuse and Mental Health Administration to support research into special risks and vulnerabilities, behavioral and biochemical assessments and intervention methodologies most useful in identifying persons at special risk and the behavioral and biochemical strategies that are most effective in ameliorating risk factors.
(2) Urges the Center for Substance Abuse Prevention to continue to support community-based prevention strategies which include: (a) Special attention to children and adolescents, particularly in schools, beginning at the pre-kindergarten level. (b) Changes in the social climate (i.e., attitudes of community leaders and the public), to reflect support of harmful drug and alcohol use prevention and treatment, eliminating past imbalances in allocation of resources to supply and demand reduction. (c) Development of innovative programs that train and involve parents, educators, physicians, and other community leaders in "state of the art" prevention approaches and skills.
(3) Urges major media programming and advertising agencies to encourage the development of more accurate and prevention-oriented messages about the effects of harmful drug and alcohol use.
(4) Supports the development of advanced educational programs to produce qualified prevention specialists, particularly those who relate well to the needs of economically disadvantaged, ethnic, racial, and other special populations.
(5) Supports investigating the feasibility of developing a knowledge base of comprehensive, timely and accurate concepts and information as the "core curriculum" in support of prevention activities.
(6) Urges federal, state, and local government agencies and private sector organizations to accelerate their collaborative efforts to develop a national consensus on prevention and eradication of harmful alcohol and drug use. [BOT Rep. H, A-89; Reaffirmed: CSA Rep. 12, A-99; Reaffirmation I-01; Reaffirmed: CSAPH Rep. 1, A-11; Modified: CSAPH Rep. 1, A-21; Reaffirmed: Res. 523, A-23]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 518
(A-25)

Introduced by: Undersea and Hyperbaric Medical Society, Laurie Gesell, MD, Jayesh Shah, MD

Subject: Mandatory Accreditation and Regular Inspections of Hyperbaric Chambers

Referred to: Reference Committee E

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Whereas, a recent tragic incident in Michigan resulted in the death of a child due to a chamber explosion in an unaccredited hyperbaric facility; and

Whereas, hyperbaric chambers pose significant risks, including fire hazards due to high oxygen concentrations, which can be mitigated by adherence to rigorous safety standards; and

Whereas, currently there is no uniformity in state regulations, with most states lacking requirements for accreditation or regular inspections of hyperbaric chambers; and

Whereas, the Food and Drug Administration recommends that patients being referred for hyperbaric oxygen therapy go to a hospital or facility that has been “inspected and is properly accredited by the Undersea and Hyperbaric Medical Society”; and

Whereas, the Undersea and Hyperbaric Medical Society is the only organization that conducts hyperbaric facility accreditations to ensure facilities meet high safety and patient care standards; and

Whereas,The Joint Commission recognizes the UHMS accreditation program as the only Complementary Accrediting Organization under their Cooperative Agreement; and

Whereas, ensuring the safety of patients undergoing hyperbaric oxygen therapy is paramount; therefore be it

RESOLVED, that our American Medical Association recommend that all states within the United States require hyperbaric chamber facilities to be accredited by the Undersea and Hyperbaric Medical Society (New HOD Policy); and be it further

RESOLVED, that our AMA advocate for at least annual inspections of hyperbaric chambers by the manufacturer or other approved biomedical equipment personnel to ensure compliance with safety standards (Directive to Take Action); and be it further

RESOLVED, that our AMA support legislative efforts to establish uniform national standards for the operation and maintenance of hyperbaric chambers. (New HOD Policy)

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

Received: 4/21/25

**REFERENCES**

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2. The Joint Commission: Complementary Agreements https://www.jointcommission.org/resources/news-and-multimedia/fact-sheets/facts-about-cooperative-accreditation-initiative/
3. UHMS Hyperbaric Facility Accreditation Program https://www.uhms.org/accreditation/accreditation-for-hyperbaric-medicine.html
4. National Board of Boiler and Pressure Vessel Inspectors https://www.nationalboard.org/PrintPage.aspx?pageID=164&ID=202
5. Hyperbaric Chambers: What they are, what they treat, risks, and accreditation https://www.clickondetroit.com/news/local/2025/01/31/hyperbaric-chambers-what-they-are-what-they-treat-risks-and-accreditation/
6. National Board of Diving and Hyperbaric Medical Technology https://nbdhmt.org/

## RELEVANT AMA POLICY

**D-270.986 Oppose Unsafe Use of "Mild Hyperbaric Therapy"**
Our American Medical Association opposes the operation of "mild hyperbaric facilities" unless and until effective treatments can be delivered safely in facilities with appropriately trained staff including physician supervision and prescription and only when the intervention has scientific support or rationale.

Our AMA will work with the U.S. Food and Drug Administration and other regulatory bodies to close facilities offering "mild hyperbaric therapy" until and unless they adopt and adhere to all established safety regulations, adhere to the established principles of the practice of hyperbaric oxygen under the prescription and oversight of a licensed and trained physician, and ensure that staff are appropriately trained and adherent to applicable safety regulations.

**D-160.916 Safe Supervision of Complex Radiation Oncology and Hyperbaric Oxygen Therapeutic Procedures**
Our AMA will advocate that: (1) radiation therapy services and hyperbaric oxygen services should be exempted from the Hospital Outpatient Prospective Payment System (HOPPS) rule requiring only general supervision of hospital therapeutic services; and (2) direct supervision of hyperbaric oxygen therapy services by a physician trained in hyperbaric oxygen services should be required by the Centers for Medicare and Medicaid Services.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 519
(A-25)

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|---|---|
| Introduced by: | Washington State, Montana, Arizona, Mississippi, Utah, American Academy of Family Physicians |
| Subject: | Framework to Convey Evidence-Based Medicine in AI Tools Used in Clinical Decision Making |
| Referred to: | Reference Committee E |

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Whereas, there are estimates that medical knowledge doubles every 73 days[1] and that 30 percent of all the data generated worldwide is estimated to be healthcare related[2]; and

Whereas, large language models utilize vast amounts of data and algorithm development is frequently proprietary and challenging to discern especially during point-of-care encounters; and

Whereas, augmented intelligence (AI) in healthcare varies from technologies with lower risk to patient safety including administrative tasks, data collection, and scribing to technologies with higher risk to patient safety including triage, chatbots, and—finally—clinical decision support; and

Whereas, the integration of AI into healthcare has the potential to enhance clinical decision-making, patient outcomes, and operational efficiencies in healthcare delivery and "Health care AI must be designed, developed, and deployed in a manner which is ethical, equitable, responsible, accurate, transparent, and evidence-based[3,4];" and

Whereas, our AMA Report of the BOT previously noted, "To best foster trust, both between physicians and developers/deployers, and between physicians and patients, use of AI that may directly impact medical decision making should be communicated to parties involved in that decision making"[3]; and

Whereas, the pace of progress in health AI will be determined by the pace of trust; and

Whereas, evidence-based medicine (EBM) is the use of high-quality clinical research in making decisions about the care of patients in which strength of recommendation taxonomy (SORT) has been used as a mechanism to convey quality of evidence[5] and Open Ethics Label (OEL) has been described as a "nutrition label" for digital products to make these products transparent and safe for consumers[6]; and

Whereas, the current Trump administration repealed President Biden's signature October 2023 AI executive order which aimed to promote safe and secure use of AI; and

Whereas, the Bipartisan House Task Force on AI emphasizes the need for a thoughtful, risk-based approach to AI governance and recommends adopting sector-specific policies and standards to address unique challenges in healthcare[7]; and

Whereas, evidence-based medicine is foundational to clinical decision-making, and AI tools should integrate and prioritize validated EBM guidelines while being rigorously tested to ensure their real-world clinical utility[8 9]; and

Whereas, evidence-based AI systems must meet rigorous criteria for clinical effectiveness, cost efficiency, and health equity to earn the trust and widespread adoption among physicians and their patients[10]; and

Whereas, there is a lack of a comprehensive framework for integrating evidence-based AI tools into clinical workflows to ensure effective implementation and to address potential risks of misinformation or misuse[3 10]; and

Whereas, the need for collaboration among healthcare delivery organizations, regulatory agencies, and technology developers has been highlighted as essential for responsible AI development and deployment[3 4]; therefore be it

RESOLVED, that our American Medical Association collaborate with stakeholders, including physicians, academic institutions, and industry leaders, to create a report by A-26 with recommendations for how AI tools used in clinical decision support convey transparency in the quality of medical evidence and the grading of medical evidence to physicians and advanced care practitioners so clinical recommendations can be accurately verified and validated. (Directive to Take Action)

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

Received: 4/9/25

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## RELEVANT AMA POLICY

### H-480.935 Assessing the Potentially Dangerous Intersection Between AI and Misinformation

1. Our American Medical Association will study and develop recommendations on the benefits and unforeseen consequences to the medical profession of large language models (LLM) such as, generative pretrained transformers (GPTs), and other augmented intelligence-generated medical advice or content, and that our AMA propose appropriate state and federal regulations with a report back at A-24.
2. Our AMA will work with the federal government and other appropriate organizations to protect patients from false or misleading AI-generated medical advice.

3. Our AMA will encourage physicians to educate our patients about the benefits and risks of consumers facing LLMs including GPTs.
4. Our AMA will support publishing groups and scientific journals to establish guidelines to regulate the use of augmented intelligence in scientific publications that include detailing the use of augmented intelligence in the methods, exclusion of augmented intelligence systems as authors, and the responsibility of authors to validate the veracity of any text generated by augmented intelligence.

**D-480-956 Use of Augmented Intelligence for Prior Authorization**
Our American Medical Association advocates for greater regulatory oversight of the use of augmented intelligence for review of patient claims and prior authorization requests, including whether insurers are using a thorough and fair process that:

1. is based on accurate and up-to-date clinical criteria derived from national medical specialty society guidelines and peer reviewed clinical literature.
2. includes reviews by doctors and other health care professionals who are not incentivized to deny care and with expertise for the service under review.
3. requires such reviews include human examination of patient records prior to a care denial.

**H-480-940 Augmented Intelligence in Health Care**
As a leader in American medicine, our American Medical Association has a unique opportunity to ensure that the evolution of augmented intelligence (AI) in medicine benefits patients, physicians, and the health care community.
To that end our AMA will seek to:

1. Leverage its ongoing engagement in digital health and other priority areas for improving patient outcomes and physicians' professional satisfaction to help set priorities for health care AI.
2. Identify opportunities to integrate the perspective of practicing physicians into the development, design, validation, and implementation of health care AI.
3. Promote development of thoughtfully designed, high-quality, clinically validated health care AI that:
    a. is designed and evaluated in keeping with best practices in user-centered design, particularly for physicians and other members of the health care team;
    b. is transparent;
    c. conforms to leading standards for reproducibility;
    d. identifies and takes steps to address bias and avoids introducing or exacerbating health care disparities including when testing or deploying new AI tools on vulnerable populations; and
    e. safeguards patients' and other individuals' privacy interests and preserves the security and integrity of personal information.
4. Encourage education for patients, physicians, medical students, other health care professionals, and health administrators to promote greater understanding of the promise and limitations of health care AI.
5. Explore the legal implications of health care AI, such as issues of liability or intellectual property, and advocate for appropriate professional and governmental oversight for safe, effective, and equitable use of and access to health care AI.

**H-480-939 Augmented Intelligence in Health Care**
Our American Medical Association supports the use and payment of augmented intelligence (AI) systems that advance the quadruple aim. AI systems should enhance the patient experience of care and outcomes, improve population health, reduce overall costs for the health care system while increasing value, and support the professional satisfaction of physicians and the health care team. To that end our AMA will advocate that:

1. Oversight and regulation of health care AI systems must be based on risk of harm and benefit accounting for a host of factors, including but not limited to: intended and reasonably expected use(s); evidence of safety, efficacy, and equity including addressing bias; AI system methods; level of automation; transparency; and, conditions of deployment.
2. Payment and coverage for all health care AI systems must be conditioned on complying with all appropriate federal and state laws and regulations, including, but not limited to those governing

patient safety, efficacy, equity, truthful claims, privacy, and security as well as state medical practice and licensure laws.

3. Payment and coverage for health care AI systems intended for clinical care must be conditioned on
    a. clinical validation.
    b. alignment with clinical decision-making that is familiar to physicians.
    c. high-quality clinical evidence.
4. Payment and coverage for health care AI systems must
    a. be informed by real world workflow and human-centered design principles.
    b. enable physicians to prepare for and transition to new care delivery models.
    c. support effective communication and engagement between patients, physicians, and the health care team.
    d. seamlessly integrate clinical, administrative, and population health management functions into workflow.
    e. seek end-user feedback to support iterative product improvement.
5. Payment and coverage policies must advance affordability and access to AI systems that are designed for small physician practices and patients and not limited to large practices and institutions. Government-conferred exclusivities and intellectual property laws are meant to foster innovation, but constitute interventions into the free market, and therefore, should be appropriately balanced with the need for competition, access, and affordability.
6. Physicians should not be penalized if they do not use AI systems while regulatory oversight, standards, clinical validation, clinical usefulness, and standards of care are in flux. Furthermore, our AMA opposes:
    a. Policies by payers, hospitals, health systems, or governmental entities that mandate use of health care AI systems as a condition of licensure, participation, payment, or coverage.
    b. The imposition of costs associated with acquisition, implementation, and maintenance of healthcare AI systems on physicians without sufficient payment.
7. Liability and incentives should be aligned so that the individual(s) or entity(ies) best positioned to know the AI system risks and best positioned to avert or mitigate harm do so through design, development, validation, and implementation. Our AMA will further advocate:
    a. Where a mandated use of AI systems prevents mitigation of risk and harm, the individual or entity issuing the mandate must be assigned all applicable liability.
    b. Developers of autonomous AI systems with clinical applications (screening, diagnosis, treatment) are in the best position to manage issues of liability arising directly from system failure or misdiagnosis and must accept this liability with measures such as maintaining appropriate medical liability insurance and in their agreements with users.
    c. Health care AI systems that are subject to non-disclosure agreements concerning flaws, malfunctions, or patient harm (referred to as gag clauses) must not be covered or paid and the party initiating or enforcing the gag clause assumes liability for any harm.
8. Our AMA, national medical specialty societies, and state medical associations:
    a. Identify areas of medical practice where AI systems would advance the quadruple aim.
    b. Leverage existing expertise to ensure clinical validation and clinical assessment of clinical applications of AI systems by medical experts.
    c. Outline new professional roles and capacities required to aid and guide health care AI systems.
    d. Develop practice guidelines for clinical applications of AI systems.
9. There should be federal and state interagency collaboration with participation of the physician community and other stakeholders in order to advance the broader infrastructural capabilities and requirements necessary for AI solutions in health care to be sufficiently inclusive to benefit all patients, physicians, and other health care stakeholders. (New HOD Policy)
10. AI is designed to enhance human intelligence and the patient-physician relationship rather than replace it.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 520
(A-25)

Introduced by: Young Physicians Section

Subject: Study of Grading Systems in AMA Board Reports

Referred to: Reference Committee E

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Whereas, the American Medical Association is committed to promoting the highest standards in patient care and medical practice; and

Whereas, evidence-based medicine is paramount to the decision-making processes that influence clinical practice and health policy; and

Whereas, the Grading of Recommendations Assessment, Development and Evaluation (GRADE) system is an example of an internationally recognized method for assessing the quality of evidence and the strength of recommendations in healthcare; and

Whereas, evidence of grading and assessment systems provide a transparent and systematic framework for ranking the quality of evidence and the strength of clinical recommendations; and

Whereas, the use of evidence grading and assessment systems would ensure that AMA board reports are based on the best available evidence, promoting trust and credibility among its members and the general public; and

Whereas, adopting a consistent method for analyzing medical evidence ensures fairness and uniformity across different reports and recommendations; therefore be it

RESOLVED, that our American Medical Association study the use of a system for assessing the quality of evidence and the strength of recommendations in board reports when appropriate. (Directive to Take Action)

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

Received: 04/21/25

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 521
(A-25)

Introduced by: New York

Subject: Warning Labels on OTC Sleep Aids

Referred to: Reference Committee E

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Whereas, over the counter (OTC) medications promoted for insomnia often contain antihistamines; and

Whereas, OTC antihistamines are documented to have severe side effects in older persons including slowing of motor reflexes leading to falls, and anticholinergic effects leading to impaired memory and possible dementia; therefore be it

RESOLVED, that our American Medical Association advocate for legislation or mandate from the appropriate regulators that over the counter (OTC) sleep medications containing antihistamines carry a warning label for adverse effects including, but not limited to for dizziness, risk of falling, and, with long term use, memory impairment, when used by elderly persons. (Directive to Take Action)

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

Received: 4/22/25

**REFERENCES**

1. https://www.verywellhealth.com/why-older-people-shouldnt-use-diphenhydramine-to-sleep-3015319#:~:text=Diphenhydramine%20can%20cause%20decreased%20reaction,fractures%20is%20a%20notable%20concern

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 522
(A-25)

Introduced by: Association for Clinical Oncology, American College of Rheumatology

Subject: Access to Important and Essential Drugs

Referred to: Reference Committee E

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Whereas, persistent shortages of essential drugs have regularly occurred for the past 10-15 years and are currently impacting patients and their care teams, particularly pediatric patients; and

Whereas, lack of predictability in the generic drug supply chain is negatively impacting patients, including disruptions or delays in treatment, potentially leading to irreversible disease progression; and

Whereas, current regulatory and market uncertainties are impacting the global supply chain and could impact access to essential drugs, increase out-of-pocket costs, and exacerbate shortages; and

Whereas, Baxter International's North Cove manufacturing plant in North Carolina was significantly impacted by Hurricane Helene in 2024, leading to shortages of IV fluids and peritoneal dialysis solutions as the plant produced about 60% or 1.5 million bags of the IV fluid used by U.S. hospitals; therefore be it

RESOLVED, that our American Medical Association work with policymakers, regulatory bodies, drug manufacturers, and the health care community to address access issues and drug shortages by identifying solutions to ensure long-term stability and preserve patient access to treatments (Directive to Take Action); and be it further

RESOLVED, that our AMA urges Congress to pass comprehensive legislation to mitigate existing drug shortages and prevent future shortages of lifesaving and life-prolonging drugs. A comprehensive approach would:

- Address economic factors that drive generic manufacturers out of the market and consider stabilizing the market with long-term contracts and guaranteed prices.
- Reward reliable U.S. manufacturing of critical and supportive medications through prices that support continued quality production and investment in continuous manufacturing or other advanced manufacturing for critical drugs and active pharmaceutical ingredients (APIs), which could include onshoring or nearshoring as components of a solution.
- Recognize potential shortages earlier by increasing the Food and Drug Administration’s (FDA) visibility into the supply chain so the agency can predict and respond to potential shortages earlier.
- Relay information about potential shortages to health systems and providers to help them prepare for and mitigate possible supply challenges. (Directive to Take Action)

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

Received: 4/22/25

**REFERENCES**
1. Drug Shortages in Oncology: ASCO Clinical Guidance for Alternative Treatments | JCO Oncology Practice
2. Advocates on Capitol Hill and Across the Country Urge Congress to Prioritize Research Funding, Fix Prior Authorization, Help End Drug Shortages - ASCO
3. HHS needs a drug shortage plan, watchdog says - Axios
4. IV shortage update: Baxter facility damage after hurricane in North Carolina 2024 | AMA Update Video | AMA

## RELEVANT AMA POLICY

### National Drug Shortages H-100.956

1. Our American Medical Association 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, and supports the use of incentives such as prioritized regulatory review, reduction of user fees, and direct grant opportunities for manufacturers seeking to invest in manufacturing processes.
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.
24. Our AMA opposes increasing drug prices or waiving fee exemptions in a manner that incentivizes a drug manufacturer to have its drug be declared in shortage.
25. Our AMA opposes the use of punitive fees on physician practices that do not maintain buffer supplies of drugs.
26. Our AMA encourages the FDA, the FTC, or other relevant oversight entities, to examine the practice of compounding pharmacies and the entities that utilize them advertising drugs actively in shortage, particularly when targeted to new patients.
27. Our AMA supports federal drug shortage prevention and mitigation programs that create payer incentives to enable practitioners and participating entities to voluntarily enter contracts directly with manufacturers that will pay more than prevailing market price for generic sterile injectable drugs at high risk of shortage to promote stable manufacturing and reliability of these products.

**Non-Profit or Public Manufacturing of Drugs to Address Generic Drug Shortages H-100.942**

1. Our American Medical Association 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. Our AMA 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.

**Drug Manufacturing Safety H-100.945**

1. Our American Medical Association supports efforts to ensure that the U.S. Food and Drug Administration (FDA) resumes inspections of all drug manufacturing facilities on a frequent and rigorous basis, as done in the past.
2. Our AMA will call for the FDA to:
    a. assure the safety of the manufacture of drugs, drug ingredients and precursors.
    b. work proactively with industry to prevent or minimize drug shortages.
    c. work with the industry to oversee the adequacy of product in the pipeline.