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REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 1-A-24

Subject: Council on Science and Public Health Sunset Review of 2014 House Policies

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

Referred to: Reference Committee E

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

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

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

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24 than its 10-year horizon if it is no longer relevant, has been superseded by a more current policy, or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

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

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33 5. The most recent policy shall be deemed to supersede contradictory past AMA policies.

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35 6. Sunset policies will be retained in the AMA historical archives.

1 RECOMMENDATION

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

Fiscal Note: \$1,000.

APPENDIX: RECOMMENDED ACTIONS

Policy Number	Title	Text	Recommendation
D-120.946	Modification to the USP Chapter 797 Guidelines as Currently Written	<ol style="list-style-type: none"> 1. Our AMA will inform physicians on the far-reaching effects of the immediate-use exception to practice and patient safety. 2. Our AMA will encourage and facilitate as a convener for all state, medical school, and specialty organization delegates to the United States Pharmacopeial Convention to protest the "immediate-use" exception to the USP Chapter 797 guidelines as currently written, including the "one-hour-rule," and seek reasonable accommodation and modification of Chapter 797 guidelines with interested stakeholders. 3. Our AMA will encourage and facilitate as a convener for all state, medical school, and specialty organization delegates to the United States Pharmacopeial Convention to protest the USP Chapter 797 guidelines as currently written, including the prohibition to enter a container no more than twice, and seek reasonable accommodation and modification of Chapter 797 guidelines with interested stakeholders. 4. Our AMA will urge The Joint Commission and other deeming organizations to suspend the enforcement of the "immediate-use" exception to USP Chapter 797 as currently written, including the "one-hour-rule" until the reconvening of the USP in June 2015. 5. Our AMA will urge the USP to employ evidence-based methods to survey current medical practice as it relates to USP Chapter 797 guidelines. (Res. 520, A-14) 	Rescind, completed. AMA's stance on USP Chapter 797 policy can be found in Policy H-120.930, "USP Compounding Rules."
D-125.987	Biosimilar Product Naming and Labeling	Our AMA urges the FDA to finalize Guidance on the naming and labeling conventions to be used for biosimilar products, including those that are deemed interchangeable. Any change in current nomenclature rules or standards should be informed by a better and more complete understanding of how such changes, including requiring a unique identifier for biologic USANs would impact prescriber attitudes and patient access, and affect post marketing surveillance. Actions that solely enhance product identification during surveillance but act as barriers to clinical uptake are counterproductive. However, because of unique product attributes, a relatively simple way to identify and track which biosimilar products have been dispensed to individual patients must be established. If unique identifiers for biosimilar USANs are required to support pharmacovigilance, they should be simple and the resulting names	Retain, still relevant. Note: May be modified by CSAPH5-A-24, "Biosimilar/Interchangeable Terminology"

		should reinforce similarities by using the same root name following standards for nonproprietary names established by the USAN Council. (CSAPH Rep. 4, A-14)	
D-125.989	Substitution of Biosimilar Medicines and Related Medical Products	Our AMA urges that State Pharmacy Practice Acts and substitution practices for biosimilars in the outpatient arena: (1) preserve physician autonomy to designate which biologic or biosimilar product is dispensed to their patients; (2) allow substitution when physicians expressly authorize substitution of <u>a biologic or biosimilar an interchangeable product</u> ; (3) limit the authority of pharmacists to automatically substitute only those biosimilar products that are deemed interchangeable by the FDA in the absence of express physician authorization to the contrary, allow substitution of the biologic or biosimilar product when (a) the biologic product is highly similar to the reference product, notwithstanding minor differences in clinically inactive components; and (b) there are no data indicating clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. (Res. 918, I-08; Modified: CSAPH Rep. 1, I-11; Modified: CSAPH Rep. 4, A-14)	Retain as amended. Amendments noted here are consistent with those currently proposed in CSAPH 5-A-24, "Biosimilar/Interchangeable Terminology"
D-135.973	Safer Chemical Policies	Our AMA will review the recommendations of the National Academies of Sciences, <u>Engineering, and Medicine</u> with respect to chemical policy reform. (Res. 415, A-14)	Retain as amended to update terminology.
D-135.985	Air Pollution and Public Health	Our AMA: (1) promotes education among its members and the general public and will support efforts that lead to significant reduction in fuel emissions in all states; and (2) will declare the need for authorities in all states to expeditiously adopt, and implement effective air pollution control strategies to reduce emissions, and this position will be disseminated to state and specialty societies. (Res. 408, A-08; Reaffirmation A-14)	Retain; still relevant.
D-135.992	Mercury Pollution	Our AMA: (1) recognizes that the trading of air pollutants is potentially harmful for vulnerable populations, and that the Clean Air Mercury Rule is inconsistent with our AMA's health protective approach to air pollution ; (2) encourages state governments to be proactive in protecting citizens from harmful mercury emissions; (3) encourages reduction in mercury use in manufacturing wherever possible, and recognize that more must be done using available and emerging technology to reduce mercury emissions; (4) recommends increased vigilance, monitoring and tracking of mercury use and emissions in	Retain as amended. Mercury air pollution is regulated under the Mercury & Air Toxics Standards, which was passed in 2012. The Clean Air Mercury Rule is no longer relevant.

		<p>chlor-alkali facilities that use mercury in manufacturing processes;</p> <p>(5) encourages the US government to assume a leadership role in reducing the global mercury burden and work toward promoting binding, health-protective international standards;</p> <p>(6) supports the Environmental Protection Agency's national mercury emissions standards for cement kilns at limits based on the latest pollution control technology; and</p> <p>(7) supports modern and strict source monitoring of mercury emissions from cement plants.</p> <p>(CSAPH Rep. 1, I-06; Appended: Res. 501, A-11; Reaffirmation A-14)</p>	
D-150.973	Powdered Caffeine and Easy Unintentional Overdose	<p>Our AMA will: (1) seek <u>supports</u> regulation or legislation to banning the sale of powdered caffeine to minors; and (2) issue a statement condemning the sale of powdered caffeine in packaging so concentrated, so difficult to measure, and in sufficient quantity that misuse and overdose is too common.</p> <p>(Res. 217, I-14)</p>	Retain as amended to remove the portion of the directive that has been accomplished; convert to H-policy.
D-150.983	Food Stamp Incentive Program	<p>Our AMA supports legislation to provide a meaningful increase in the value of <u>SNAP food stamps</u> when used to purchase fruits and vegetables.</p> <p>(Res. 405, A-07; Reaffirmation A-13; Reaffirmation A-14)</p>	Retain as amended to update terminology.
D-190.972	Physician Credit Card Payments by Health Insurance Companies	<p>Our AMA will consider legislation on behalf of physicians that any credit card transaction/bank fees are paid by the insurer and not the health care provider.</p> <p>(Res. 225, I-14)</p>	Retain; still relevant.
D-20.993	Promotion of Rapid HIV Test	<p>Our AMA will work with any and all local and state medical societies, and other interested US and international organizations, to increase access to and utilization of Food and Drug Administration-approved rapid HIV testing in accordance with the quality assurance guidelines for rapid HIV testing developed by the Centers for Disease Control and Prevention. Additionally, pre- and post-test counseling should be performed in accordance with guidelines established by the CDC.</p> <p>(Res. 511, A-05; Modified: CCB/CLRPD Rep. 2, A-14)</p>	Retain; still relevant.
D-440.943	Obstructive Sleep Apnea	<p>Our AMA: (1) recognizes Obstructive Sleep Apnea (OSA) as a major public health issue; (2) encourages a national public education campaign by appropriate federal agencies and relevant advocacy groups; (3) encourage research into the association of OSA with metabolic, cardiovascular, respiratory, and other diseases; and (4) encourages that all physicians become knowledgeable about the diagnosis and management of OSA.</p> <p>(Res. 521, A-09; Reaffirmed: Res. 107, A-14)</p>	Retain; convert to H-policy.

<p>D-450.988</p>	<p>Performance Measures for Evidence-Based Medicine</p>	<p>Our AMA will continue to ensure the quality of medical care through the appropriate use of evidence-based clinical performance measures. (Res. 506, A-04; Reaffirmed: CSAPH Rep. 1, A-14)</p>	<p>Retain; convert to H-policy.</p>
<p>D-460.969</p>	<p>Navajo Birth Cohort Study</p>	<p>1. Our AMA recognizes the public health importance of the Navajo Birth Cohort Study for our Native American population and other populations exposed to uranium. 2. Our AMA will urgently endeavor to convene key stakeholders involved with the Navajo Birth Cohort Study and appropriate high-level officials of the Centers for Disease Control and Prevention, with the goal of achieving a resolution of any issues that have prevented the release of full funding to the university contracted to perform this study, as mandated by Congress. (Res. 932, I-14)</p>	<p>Retain as amended; convert to H-Policy. The study is ongoing, so funding issues appear to have been addressed.</p>
<p>D-460.979</p>	<p>Physicians and Clinical Trials</p>	<p>Our AMA supports elimination of the use of restrictive covenants or clauses that interfere with scientific communication in agreements between pharmaceutical companies or manufacturers of medical instruments, equipment and devices, and physician researchers. (Res. 610, I-04; Modified: CSAPH Rep. 1, A-14)</p>	<p>Retain; convert to H-policy.</p>
<p>D-485.999</p>	<p>Unrealistic Expectations from Surgery on Television</p>	<p>Our AMA opposes television programs that minimize the seriousness and risks of surgery and distort patient expectations. (Res. 609, I-04; Modified: CSAPH Rep. 1, A-14)</p>	<p>Retain; convert to H-policy.</p>
<p>D-60.969</p>	<p>Legal Protection and Social Services for Commercially Sexually Exploited Youth</p>	<p>Our AMA will work with state medical societies and specialty societies to: (1) where appropriate, advocate for legal protection and alternatives to incarceration for commercially sexually exploited youth as an alternative to prosecution for crimes related to their sexual or criminal exploitation; and (2) encourage the development of appropriate and comprehensive services as an alternative to criminal detention in order to overcome barriers to necessary services and care for commercially sexually exploited youth. (Res. 4, I-14)</p>	<p>Rescind. Addressed in current policies H-60.912 and H-65.948.</p>
<p>D-60.976</p>	<p>Childhood Anaphylactic Reactions</p>	<p>Our AMA will: (1) urge all schools, from preschool through 12th grade, to: (a) develop Medical Emergency Response Plans (MERP); (b) practice these plans in order to identify potential barriers and strategies for improvement; (c) ensure that school campuses have a direct communication link with an emergency medical system (EMS); (d) identify students at risk for life-threatening emergencies and ensure these children have an individual emergency care plan that is formulated with input by a physician; (e) designate roles and responsibilities among school staff for handling potential life-threatening emergencies, including administering medications, working with EMS and local emergency departments, and contacting</p>	<p>Retain; still relevant.</p>

		<p>families; (f) train school personnel in cardiopulmonary resuscitation; (g) adopt the School Guidelines for Managing Students with Food Allergies distributed by FARE (Food Allergy Research & Education); and (h) ensure that appropriate emergency equipment to deal with anaphylaxis and acute asthmatic reactions is available and that assigned staff are familiar with using this equipment; (2) work to expand to all states laws permitting students to carry prescribed epinephrine or other medications prescribed by their physician for asthma or anaphylaxis; (3) support increased research to better understand the causes, epidemiology, and effective treatment of anaphylaxis; (4) urge the Centers for Disease Control and Prevention to study the adequacy of school personnel and services to address asthma and anaphylactic emergencies; (5) urge physicians to work with parents and schools to ensure that all their patients with a food allergy have an individualized emergency plan; and (6) work to allow all first responders to carry and administer epinephrine in suspected cases of anaphylaxis. (CSAPH Rep. 1, A-07; Modified: CCB/CLRPD Rep. 2, A-14)</p>	
<p>H-10.963</p>	<p>Safe In-Line Skating</p>	<p>1. Our AMA encourages physicians to counsel patients, and their parents when appropriate, that full protective equipment should be worn and appropriate safety measures be taken to prevent in-line skating injuries. Consistent with recommendations of the American Academy of Pediatrics, prevention efforts should include the following: (a) Full protective gear should be worn at all times. This would include wrist guards, elbow pads, kneepads, and a helmet. The helmet should be certified by the ASTM, the ANSI, or the Snell Foundation. (b) Unsafe activities such as hitching or truck surfing, which is latching onto a moving vehicle, should be avoided. (c) Training for beginners should be encouraged, and novice skaters should start in an indoor or outdoor rink rather than on the street. (d) Skaters should not skate in the dark and should learn to look for road debris or defects that could cause them to lose their balance. (e) Skaters, especially children with balance problems, physical disabilities, or uncorrected vision or hearing problems should do so in a rink or another protected place.</p> <p>2. Our AMA encourages federal agencies and industries to support research on patterns of equipment use and frequency of protective equipment use for in-line skating.</p> <p>3. Our AMA will continue to work with the Consumer Product Safety Commission, Centers for Disease Control and Prevention, national in-line skating organizations, and medical specialty</p>	<p>Retain; still relevant.</p>

		<p>societies, the AMA Alliance and the Federation to encourage in-line skaters to wear protective equipment.</p> <p>4. Our AMA encourages medical specialty societies and state and local medical societies to advocate for state and local legislation to improve the safety of in-line skating through: (a) the use of appropriate protective equipment (especially helmets); (b) the designation of protected areas for in-line skating; (c) prohibitions against hitching a ride behind a moving vehicle; (d) the assurance that protective equipment is available at skating rental shops; and (e) the provision of training and educational materials. Such legislation should include a surveillance component to monitor compliance.</p> <p>(CCB/CLRPD Rep. 3, A-14)</p>	
<p>H-10.964</p>	<p>Helmets for Riders of Motorized and Non-motorized Cycles</p>	<p>General Helmet Use: Our AMA: (1) encourages physicians to counsel their patients who ride motorized and non-motorized cycles to use approved helmets and appropriate protective clothing while cycling; (2) encourages patients and families to inform and train children about safe cycle-riding procedures, especially on roads and at intersections, the need to obey traffic laws, and the need for responsible behavior; (3) encourages community agencies, such as those involving law enforcement, schools, and parent-teacher organizations, to promote training programs for the responsible use of cycles; (4) urges manufacturers to improve the safety and reliability of the vehicles they produce and to support measures to improve cycling safety; (5) advocates further research on the effectiveness of helmets and on the health outcomes of community programs that mandate their use; (6) encourages efforts to investigate the impact of helmet use by riders of motorcycles and all bicycles, in order to establish the risk of major medical trauma from not wearing helmets, the costs added to the health care system by such behavior, and the payers of these added costs (i.e., private insurance, uncompensated care, Medicare, Medicaid, etc.); (7) supports the exploration of ways to ensure the wearing of helmets through the use of disincentives or incentives such as licensing fees, insurance premium adjustments and other payment possibilities.</p> <p>Bicycles: Our AMA: (1) actively supports bicycle helmet use and encourages physicians to educate their patients about the importance of bicycle helmet use; (2) encourages the manufacture, distribution, and utilization of safe, effective, and reasonably priced bicycle helmets; and (3) encourages the availability of helmets at the point of bicycle purchase.</p>	<p>Retain; still relevant.</p>

		<p>Scooters: Our AMA: (1) recommends the use of protective gear (certified helmets, elbow and knee pads, closed-toe shoes) for riders of scooters, especially children and adolescents; (2) encourages physicians to counsel patients, and their parents when appropriate, that full protective equipment should be worn and appropriate safety measures should be taken to prevent scooter injuries (e.g., riding away from traffic, and close supervision of riders under the age of eight); and (3) urges companies that manufacture or sell scooters to include appropriate information about the safe use of scooters on the scooters themselves, on or inside scooter packaging, on their web sites, and at the point of sale.</p> <p>Motorcycles: Our AMA: (1) encourages physicians to be aware of motorcycle risks and safety measures and to counsel their patients who ride motorcycles to wear appropriate protective gear and helmets that meet federal safety standards, receive appropriate training in the safe operation of their motorcycle, comply with state licensing laws, and avoid riding a motorcycle while under the influence of alcohol and other drugs; (2) endorses the concept of legislative measures to require the use of helmets when riding or driving a motorcycle; (3) supports federal regulatory rules to make the receipt of federal highway funds by a state dependent on passage of mandatory motorcycle helmet laws by that state; (4) urges constituent societies to support the enactment or preservation of state motorcycle helmet laws; and (5) supports rider education legislation, which is more easily implemented and more effective than legislation requiring manufacturers to emphasize the dangers of operating motorcycles. (CCB/CLRPD Rep. 3, A-14)</p>	
<p>H-120.936</p>	<p>Improve Safety of Mail-Ordered Medication</p>	<p>Our AMA supports the establishment of national guidelines for mail-order pharmacies to ensure that medications reach patients in a safe and timely manner with full potency, and that when medication is damaged or loses potency during shipment, it should be replaced by the pharmacy at no cost to the patient. (Res. 917, A-14)</p>	<p>Retain; still relevant.</p>
<p>H-120.962</p>	<p>National Mail Order Pharmacy Practices</p>	<p>1. The AMA insists that mail-order pharmacy companies respect the prescribing authority of physicians and dispense prescription medications only in the amounts prescribed; and recommends that mail order pharmacy companies charge only a reasonable and small shipping and handling fee per shipment in order not to encourage patients to request amounts of medications greater than those warranted by their physician's best judgment. 2. Our AMA opposes charging patients more than one co-pay for multiple prescriptions of the same</p>	<p>Retain as amended to remove clause that has been accomplished.</p>

		<p>or varying doses of a long-term medication within a 90-day period when evidence-based medicine dictates that less than 90-day prescriptions should be written during the initialization and dose stabilization of a newly prescribed long-term medication or during change in dosing of a long-term medication currently being taken.</p> <p>3. Our AMA will make traditional pharmacies, including national chains, mail order pharmacies, appropriate insurance carriers, and pharmaceutical benefit management companies aware of its policy opposing the charging of patients more than one co-pay for multiple prescriptions of the same or varying doses of a long term medication within a 90 day period when evidence based medicine dictates that less than 90 day prescriptions should be written during the initialization and dose stabilization of a newly prescribed long term medication or during change in dosing of a long term medication currently being taken.</p> <p>(Sub. Res. 506, I-96; Reaffirmed: CSAPH Rep. 3, A-06; Appended: Res. 121, A-07; Reaffirmed: BOT Rep. 8, A-11; Reaffirmation A-14)</p>	
<p>H-120.968</p>	<p>Medication (Drug) Errors in Hospitals</p>	<p>(1) Our AMA encourages individual physicians to minimize medication errors by adhering to the following guidelines when prescribing medications:</p> <p>(a) Physicians should stay abreast of the current state of knowledge regarding optimal prescribing through literature review, use of consultations with other physicians and pharmacists, participation in continuing medical education programs, and other means.</p> <p>(b) Physicians should evaluate the patient's total status and review all existing drug therapy before prescribing new or additional medications (e.g., to ascertain possible antagonistic drug interactions).</p> <p>(c) Physicians should evaluate and optimize patient response to drug therapy by appropriately monitoring clinical signs and symptoms and relevant laboratory data; follow-up and periodically reevaluate the need for continued drug therapy.</p> <p>(d) Physicians should be familiar with the hospital's medication-ordering system, including the formulary system; the drug use review (DUR) program; allowable delegation of authority; procedures to alert nurses and others to new drug orders that need to be processed; standard medication administration times; and approved abbreviations.</p> <p>(e) Written drug or prescription orders (including signatures) should be legible. Physicians with poor handwriting should print or type medication orders if direct order entry capabilities for computerized systems are unavailable.</p>	<p>Retain; still relevant.</p>

		<p>(f) Medication orders should be complete and should include patient name; drug name (generic drug name or trademarked name if a specific product is required); route and site of administration; dosage form (if applicable); dose; strength; quantity; frequency of administration; and prescriber's name. In some cases, a dilution, rate, and time of administration should be specified. Physicians should review all drug orders for accuracy and legibility immediately after they have prescribed them.</p> <p>(g) Medication orders should be clear and unambiguous. Physicians should: (i) write out instructions rather than use nonstandard or ambiguous abbreviations (e.g., write "daily" rather than "qd" which could be misinterpreted as "qid" or "od"); (ii) not use vague instructions, such as "take as directed"; (iii) specify exact dosage strengths (such as milligrams) rather than dosage form units (such as one vial) (an exception would be combination products, for which the number of dosage form units should be specified); (iv) prescribe by standard nomenclature, using the United States Adopted Names (USAN)-approved generic drug name, official name, or trademarked name (if a specific product is required) and avoid locally coined names, chemical names, unestablished abbreviated drug names (e.g., AZT), acronyms, and apothecary or chemical symbols; (v) always use a leading "0" to precede a decimal expression of less than one (e.g., 0.5 ml), but never use a terminal "0" (e.g., 5.0 ml); (vi) avoid the use of decimals when possible (e.g., prescribe 500 mg instead of 0.5 g); (vii) spell out the word "units" rather than writing "u"; (viii) and use the metric system. Instructions with respect to "hold" orders for medications should be clear.</p> <p>(h) Verbal medication orders should be reserved only for those situations in which it is impossible or impractical for the prescriber to write the order or enter it in a computer. Verbal orders should be dictated slowly, clearly, and articulately to avoid confusion. The order should be read back to the prescriber by the recipient (e.g., nurse, pharmacist); when read back, the recipient should spell the drug name and avoid abbreviations when repeating the directions. A written copy of the verbal order should be placed in the patient's medical record and later confirmed by the prescriber in accordance with applicable state regulations and hospital policies.</p> <p>(2) Our AMA encourages the hospital medical staff to take a leadership role in their hospital, and in collaboration with pharmacy, nursing, administration, and others, to develop and improve organizational systems for monitoring, reviewing,</p>	
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		and reporting medication errors and, after identification, to eliminate their cause and prevent their recurrence. (BOT Rep. 11, A-94; Reaffirmed by Sub. Res. 508, I-94; Reaffirmed and Modified: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	
H-120.975	Certifying Indigent Patients Unable to Pay for Pharmaceutical Manufacturers' Free Drug Programs	Our AMA: (1) supports Pharmaceutical Research and Manufacturers of America (PhRMA) programs for indigent patients and the development of a universal application process, eligibility criteria and form for all prescription drug patient-assistance programs to facilitate enrollment of patients and physicians; (2) encourages PhRMA to provide information to physicians and hospital medical staffs about member programs that provide pharmaceuticals to indigent patients; (3) urges drug companies to develop user-friendly and culturally sensitive uniform centralized policies and procedures for certifying indigent patients for free or discounted medications for patients unable to pay; and (4) opposes the practice of charging patients to apply for or gain access to pharmaceutical assistance programs. (Sub. Res. 105, I-92; Sub. Res. 507, A-96; Appended: Sub. Res. 513, I-97; Reaffirmation I-98; Reaffirmation I-00; Reaffirmation A-01; Amended: Res. 513, A-02; Reaffirmed and Appended: Sub. Res. 705, I-03; Reaffirmed and Modified: BOT Rep. 13, A-04; Reaffirmation I-04; Modified: CSAPH Rep. 1, A-14)	Retain as amended to include person-first language.
H-125.980	Abbreviated Pathway for Biosimilar Approval	Our AMA supports FDA implementation of the Biologics Price Competition and Innovation Act of 2009 in a manner that 1) places appropriate emphasis on promoting patient access, protecting patient safety, and preserving market competition and innovation; 2) includes planning by the FDA and the allocation of sufficient resources to ensure that physicians understand the distinctions between biosimilar products that are considered highly similar, and those that are deemed interchangeable. Focused educational activities must precede and accompany the entry of biosimilars into the U.S. market, both for physicians and patients; and 3) includes compiling and maintaining an official compendium of biosimilar products, biologic reference products, and their related interchangeable biosimilars as they are developed and approved for marketing by the FDA. (Res. 220, A-09; Reaffirmation A-11; Modified: CSAPH Rep. 1, I-11; Modified: CSAPH Rep. 4, A-14)	Retain; still relevant. Note: May be modified by CSAPH5-A-24, "Biosimilar/Interchangeable Terminology."
H-130.936	Tornado Safety and Manufactured Homes	Our AMA believes that: 1. Owners of manufactured home parks should provide a plan, developed with and approved by local authorities, for the evacuation and sheltering of residents of the park in severe weather events	Retain; still relevant.

		<p>such as tornadoes, high winds, or floods. The plan should advise residents of the vulnerability of manufactured homes in tornadoes and other extreme wind events and that evacuation to a safer location is necessary. The shelter or evacuation plan should be posted conspicuously in the park and the park owner should provide each resident with a copy of the approved shelter or evacuation plan.</p> <p>2. State and local government authorities in regions at increased risk for tornadoes and other extreme wind events should enact measures to either provide, or require owners of manufactured home parks in their jurisdiction to provide, as appropriate, an approved common storm shelter or safe room for all residents of manufactured homes in the park as protection against tornadoes and other extreme wind events.</p> <p>3. Research is needed to enhance the design and construction of manufactured homes and manufactured home tie down/anchoring systems to withstand extreme wind forces and wind-blown debris.</p> <p>4. Federal, state, regional, and local authorities should coordinate policies, processes, and procedures to ensure that manufactured homes are installed and inspected in accordance with established guidelines and standards, including requirements for the installation and inspection of tie down/anchoring systems.</p> <p>5. Incentives should be developed for all homeowners (including those who live in manufactured homes), businesses, and local governments in regions at increased risk for tornadoes and other extreme wind events for the installation of home or community safe rooms and storm shelters, in accordance with federal and professional guidelines and standards.</p> <p>6. All citizens should consider purchasing a NOAA Weather Radio All Hazards public alert radio for use in disasters and other emergency situations. Citizens also should develop a plan for where they will go and what they will do when a severe weather alert is issued. (CSAPH Rep. 3, I-14)</p>	
<p>H-135.991</p>	<p>Clean Air</p>	<p>(1) The AMA supports setting the national primary and secondary ambient air quality standards at the level necessary to protect the public health. Establishing such standards at the level necessary to protect the public health. Establishing such standards at a level "allowing an adequate margin of safety," as provided in current law, should be maintained, but more scientific research should be conducted on the health effects of the standards currently set by the EPA.</p>	<p>Retain as amended. The deleted sentence in first clause is not a complete sentence and does not add value to the policy as written. The third resolve recommended for deletion is redundant with existing and newer AMA policy H-135.949, with the newer resolve having more specific language on encouraging regulations that reduce hazardous emissions.</p>

		<p>(2) The AMA supports continued protection of certain geographic areas (i.e., those with air quality better than the national standards) from significant quality deterioration by requiring strict, but reasonable, emission limitations for new sources.</p> <p>(3) The AMA endorses a more effective hazardous pollutant program to allow for efficient control of serious health hazards posed by airborne toxic pollutants.</p> <p>(4) The AMA believes that more research is needed on the causes and effects of acid rain, and that the procedures to control pollution from another state need to be improved.</p> <p>(5) The AMA believes that attaining the national ambient air quality standards for nitrogen oxides and carbon monoxide is necessary for the long-term benefit of the public health. Emission limitations for motor vehicles should be supported as a long-term goal until appropriate peer-reviewed scientific data demonstrate that the limitations are not required to protect the public health.</p> <p>(BOT Rep. R, A-82; Reaffirmed: CLRPD Rep. A, I-92; Amended: CSA Rep. 8, A-03; Reaffirmation I-06; Reaffirmed in lieu of Res. 509, A-09; Reaffirmation I-09; Reaffirmation A-14)</p>	
<p>H-145.977</p>	<p>Use of Conducted Electrical Devices by Law Enforcement Agencies</p>	<p>Our AMA: (1) recommends that law enforcement departments and agencies should have in place specific guidelines, rigorous training, and an accountability system for the use of conducted electrical devices (CEDs) that is modeled after available national guidelines; (2) encourages additional independent research involving actual field deployment of CEDs to better understand the risks and benefits under conditions of actual use. Federal, state, and local agencies should accurately report and analyze the parameters of CED use in field applications; and (3) policy is that law enforcement departments and agencies have a standardized protocol developed with the input of the medical community for the evaluation, management and post-exposure monitoring of subjects exposed to CEDs.</p> <p>(CSAPH Rep. 6, A-09; Modified: Res. 501, A-14)</p>	<p>Retain; still relevant.</p>
<p>H-15.950</p>	<p>Child Safety Seats - Public Education and Awareness</p>	<p>Our AMA supports efforts to require child safety seat manufacturers to include information about the importance of rear-facing safety seats until children are two <u>at least four</u> years of age or until they reach the maximum height or weight specifications of their car seat, at which time they should be placed in a forward-facing child safety system with a harness as recommended by the American Academy of Pediatrics.</p> <p>(Res 922, I-14)</p>	<p>Retain as amended to bring the age recommendation in line with current AAP recommendations.</p>
<p>H-15.951</p>	<p>All-Terrain Vehicles</p>	<p>Our AMA: supports publicizing the dangers of all-terrain vehicles, especially to persons unlicensed to drive other vehicles; encourages manufacturers and</p>	<p>Retain; still relevant.</p>

		dealers of ATVs to provide information regarding the safe operation of such vehicles; and seeks federal legislation to require sellers of all-terrain vehicles in the United States to promote the sale and use of suitable helmets to be used when operating or riding as a passenger on ATVs; and federal and state legislation and/or regulation to maximize safety of ATV operation including but not limited to (a) wearing suitable helmets and protective gear when operating or riding as a passenger on an ATV, (b) providing some safety instruction and training to all operators of ATVs, and (c) ensuring appropriate licensure for all operators of ATVs. (CCB/CLRPD Rep. 3, A-14)	
H-15.986	Automatic (i.e., Passive) Restraints to Prevent Injuries and Deaths from Motor Vehicle Accidents	The AMA (1) supports legislation to promote availability of effective seat belts in school buses in the U.S.; and (2) supports legislative action to promote availability of effective seat belts in all motor vehicles in public use (e.g., public and private buses, taxicabs, and any other vehicles carrying passengers). (Sub. Res. 2, A-84; Reaffirmed by CLRPD Rep. 3 - I-94; Reaffirmation A-04; Reaffirmed: BOT Rep. 29, A-04; Modified: CSAPH Rep. 1, A-14)	Retain; still relevant.
H-150.931	Payment for Nutrition Support Services	Our AMA recognizes the value of nutrition support teams services and their role in positive patient outcomes and supports payment for the provision of their services. (Res. 705, A-14)	Retain; still relevant.
H-150.948	Increasing Awareness of Nutrition Information and Ingredient Lists	Our AMA supports federal federal 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)	Retain as amended so as not limit legislation to the federal level.
H-155.988	Public Health and Safety Awareness	The AMA believes that attention to personal health and safety can dramatically improve well-being and reduce health care costs. (Res. 42, I-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CMS Rep. 5, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Retain; still relevant.
H-170.972	Role of Physicians in Improving Adolescent Health	The AMA supports programs that encourage teen health and supports the involvement of medical students, residents, and other physicians in educational efforts to enhance teen health. (Res. 431, A-94; Reaffirmed and Modified: CSA Rep. 6, A-04; Modified: CSAPH Rep. 1, A-14)	Retain; still relevant.

H-170.985	Science, Technology, Engineering and Mathematics Education	Our AMA is committed to working with other concerned organizations and agencies to improve science, technology, engineering and mathematics (STEM) education and literacy in the nation, and to increase interest in STEM on the part of the nation's youth, particularly underrepresented minorities. (Res. 2, A-88; Reaffirmed: Sunset Report, I-98; Modified and Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmed in lieu of Res. 514, A-09; Reaffirmed in lieu of Res. 524, A-09; Modified: Res. 516, A-14)	Retain; still relevant.
H-175.995	Hair Analysis - A Potential for Medical Abuse	The AMA opposes chemical analysis of the hair as a determinant of the need for medical therapy and supports informing the American public and appropriate governmental agencies of this unproven practice and its potential for health care fraud. (Sub. Res. 67, I-84; Reaffirmed by CLRPD Rep. 3 - I-94; Reaffirmed: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Retain; still relevant.
H-245.981	Vitamin K Prophylaxis in Newborn Infants	The AMA supports the intramuscular administration of a single dose of 0.5-1 mg of vitamin K1 in neonates at birth to prevent vitamin K deficiency bleeding. (Res. 514, A-94; Reaffirmed: CSA Rep. 6, A-04; Modified: CSAPH Rep. 1, A-14)	Retain; still relevant.
H-25.994	Increased Liaison, Communication and Educational Efforts with the Elderly	The AMA supports (1) increasing communications and understanding between organized medicine and the elderly; (2) continuing contact with organizations such as the AARP, offering speakers for their meetings, and pursuing other steps to improve their understanding of physicians' problems and concerns; and (3) encouraging state and county medical societies to undertake similar efforts to increase liaison with the elderly. (Res. 133, A-84; Reaffirmed by CLRPD Rep. 3 - I-94; Reaffirmed: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Retain; still relevant.
H-280.962	Dehydration	Evaluation and Management in Older Adults: The policy of the AMA is that undergraduate, graduate and continuing education programs for physicians and allied health professionals be encouraged to teach the science of dehydration in older adults; and that assessment of hydration status and potential for dehydration be incorporated when appropriate in hospital discharge planning, home health agency and nursing home assessments. The AMA: (1) encourages development of programs to increase physician awareness and skills in the evaluation of dehydration in long-term care residents and older adults living in the community setting; (2) encourages a leadership role for physicians as active team participants in long-term care facilities	Retain; still relevant.

		<p>regarding quality assurance programs assessing the hydration status of residents and recommend appropriate reimbursement for those services; (3) encourages development of programs to increase awareness of the potential problem of dehydration in community residents; (4) encourages community nursing facilities that do not provide daily clinical laboratory services to make them available for residents so that necessary data on patient status can be provided promptly, even on a STAT basis. The ready availability of laboratory services could present unnecessary hospitalizations; and (5) encourages the expansion of research efforts in this area. (CSA Rep. 1, A-94; Reaffirmation A-04; Reaffirmed: CSAPH Rep. 1, A-14)</p>	
<p>H-30.936</p>	<p>Prevention of Impaired Driving</p>	<p>Our AMA: (1) acknowledges that all alcohol consumption, even at low levels, has a negative impact on driver skills, perceptions, abilities, and performance and poses significant health and safety risks; (2) supports 0.04 percent blood-alcohol level as per se illegal for driving, and urges incorporation of that provision in all state drunk driving laws; and (3) supports 21 as the legal drinking age, strong penalties for providing alcohol to persons younger than 21, and stronger penalties for providing alcohol to drivers younger than 21. Education: Our AMA: (1) favors public information and education against any drinking by drivers; (2) supports efforts to educate physicians, the public, and policy makers about this issue and urges national, state, and local medical associations and societies, together with public health, transportation safety, insurance, and alcohol beverage industry professionals to renew and strengthen their commitment to preventing alcohol-impaired driving; (3) encourages physicians to participate in educating patients and the public about the hazards of chemically impaired driving; (4) urges public education messages that now use the phrase "drunk driving," or make reference to the amount one might drink without fear of arrest, be replaced with messages that indicate that "all alcohol use, even at low levels, impairs driving performance and poses significant health and safety risks;" (5) encourages state medical associations to participate in educational activities related to eliminating alcohol use by adolescents; and (6) supports and encourages programs in elementary, middle, and secondary schools, which provide information on the dangers of driving while under the influence of alcohol, and which emphasize that teenagers who drive should drink no alcoholic beverages whatsoever; and will continue to work with private and civic groups</p>	<p>Retain as amended as on-board devices or ignition interlock devices are now well supported by evidence and recommended the Community Preventive Services Task Force (CPSTF) for people who have been convicted of drunk driving.</p>

		<p>such as Mothers Against Drunk Driving (MADD) to achieve those goals.</p> <p>Legislation: Our AMA: (1) supports the development of model legislation which would provide for school education programs to teach adolescents about the dangers of drinking and driving and which would mandate the following penalties when a driver under age 21 drives with any blood alcohol level (except for minimal blood alcohol levels, such as less than .02 percent, only from medications or religious practices): (a) for the first offense - mandatory revocation of the driver's license for one year and (b) for the second offense - mandatory revocation of the driver's license for two years or until age 21, whichever is greater; (2) urges state medical associations to seek enactment of the legislation in their legislatures; (3) urges all states to pass legislation mandating all drivers convicted of first and multiple DUI offenses be screened for alcoholism and provided with referral and treatment when indicated; (4) urges adoption by all states of legislation calling for administrative suspension or revocation of driver licenses after conviction for driving under the influence, and mandatory revocation after a specified number of repeat offenses; and (5) encourages passage of state traffic safety legislation that mandates screening for substance use disorder for all DUI offenders, with those who are identified with substance use disorder being strongly encouraged and assisted in obtaining treatment from qualified physicians and through state and medically certified facilities.</p> <p>Treatment: Our AMA: (1) encourages that treatment of all convicted DUI offenders, when medically indicated, be mandated and provided but in the case of first-time DUI convictions, should not replace other sanctions which courts may levy in such a way as to remove from the record the occurrence of that offense; and (2) encourages that treatment of repeat DUI offenders, when medically indicated, be mandated and provided but should not replace other sanctions which courts may levy. In all cases where treatment is provided to a DUI offender, it is also recommended that appropriate adjunct services should be provided to or encouraged among the family members actively involved in the offender's life;</p> <p>Repeat Offenders: Our AMA: (1) recommends the following measures be taken to reduce repeat DUI offenses: (a) aggressive measures be applied to first-time DUI offenders (e.g., license suspension and administrative license revocation), (b) stronger penalties be leveled against repeat offenders, including second-time offenders, (c) such legal sanctions must be linked, for all offenders, to substance abuse assessment and treatment services,</p>	
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		<p>to prevent future deaths in alcohol-related crashes and multiple DUI offenses; and (2) calls upon the states to coordinate law enforcement, court system, and motor vehicle departments to implement forceful and swift penalties for second-time DUI convictions to send the message that those who drink and drive might receive a second chance but not a third.</p> <p>On-board devices: Our AMA: (1) supports further testing of on-board devices <u>or ignition interlock devices</u> to prevent the use of motor vehicles by intoxicated drivers; this testing should take place among the general population of drivers, as well as among drivers having alcohol-related problems; (2) encourages motor vehicle manufacturers and the U.S. Department of Transportation to monitor the development of ignition interlock technology, and plan for use of such systems by the general population, when a consensus of informed persons and studies in the scientific literature indicate the systems are effective, acceptable, reasonable in cost, and safe; and (3) supports continued research and testing of devices which may incapacitate vehicles owned or operated by DUI offenders without needlessly penalizing the offender's family members. (CCB/CLRPD Rep. 3, A-14)</p>	
H-365.978	Adult Film Industry Worker Safety and Health	<p>Our AMA: (1) supports legislation that would require the mandatory use of condoms in the production of adult films; (2) supports legislation that would improve the ability of local health departments and Occupational Safety and Health Administration (OSHA) to investigate and control occupational exposures to infectious diseases and enforce workplace regulations in a timely manner; and (3) urges that existing OSHA and other occupational standards be vigorously enforced to reduce exposure to infectious diseases within the adult film industry. (Res. 407, A-10; Reaffirmation A-14)</p>	Retain; still relevant.
H-370.966	Amend Federal Law to Allow Clinical Research on the Safety and Effectiveness of HIV-Infected-to-HIV-Infected Organ Transplantation	<p>Our AMA adopts a policy position in support of amending the Federal National Organ Transplant Act of 1984 (42 U.S.C. ? 274) to allow for clinical research to fully evaluate the clinical risks and benefits of HIV-infected organ donation to HIV-infected patients who elect to accept such organs and will work to support introduction and enactment of legislation to amend the Federal National Organ Transplant Act of 1984 (42 U.S.C. ? 274) to allow for clinical research to fully evaluate the clinical risks and benefits of HIV-infected organ donation to HIV-infected patients who elect to accept such organs. (Res. 2, I-11; Reaffirmed in lieu of Res. 5, I-14)</p>	Rescind, accomplished. This was accomplished by the HOPE Act, which AMA supported.
H-370.974	Working Toward an Increased	The AMA supports efforts to increase the number of all potential bone marrow donors registered in	Retain; still relevant.

	Number of Minorities Registered as Potential Bone Marrow Donors	national bone marrow registries, especially minority donors, to improve the odds of successful HLA matching and bone marrow transplantation. (Res. 501, I-94; Reaffirmed: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	
H-440.836	Role of Pharmacists in Improving Immunization Rates	Our AMA believes that: 1. Physicians and medical professional organizations should support state and federal efforts to engage pharmacists in vaccinating target populations that have difficulty accessing immunizations in a medical home. Before administration of a vaccine, pharmacists should assess the immunization status of the patient, which includes checking an immunization registry when one exists. Pharmacists should ensure that a record of vaccine administration is transmitted to the patient's primary care physician and documented in the immunization registry, and that written or electronic documentation is provided to the patient. 2. Vaccination programs in pharmacies should promote the importance of having a medical home to ensure appropriate and comprehensive preventive care, early diagnosis, and optimal therapy. Physicians and pharmacists should work together in the community to: (a) establish referral systems to facilitate appropriate medical care if the patient's conditions or symptoms are beyond the scope of services provided by the pharmacies; and (b) encourage patients to contact a primary care physician to ensure continuity of care. 3. State educational requirements for pharmacists who administer vaccines should be based on ACIP recommendations and recognized standards and guidelines derived with input from physicians and pharmacists with demonstrated expertise in immunization practices. (CSAPH Rep. 4, I-14)	Retain; still relevant.
H-440.837	Reducing Salmonella Outbreaks	Our AMA supports USDA and FDA efforts to improve standards for Salmonella testing and sampling in chicken slaughter facilities and other food processing plants to reduce human Salmonella infection. (Res. 506, A-14)	Retain; still relevant.
H-440.838	Genomic-Based Approaches to the Risk Assessment, Management and Prevention of Type 2 Diabetes	Our AMA encourages continued research into the potential of genomic information to improve risk assessment, management and prevention of type 2 diabetes, and will report back on important advances as appropriate. (CSAPH Rep. 2, A-14)	Retain; still relevant.
H-440.884	Food Allergic Reactions in Schools and Airplanes	Our AMA recommends that all: (1) schools provide increased student and teacher education on the danger of food allergies; (2) schools have a set of emergency food allergy guidelines and emergency anaphylaxis kits on the	Retain; still relevant.

		<p>premises, and that at least one member of the school administration be trained and certified in the indications for and techniques of their use; and (3) commercial airlines have a set of emergency food allergy guidelines and emergency anaphylaxis kits on the premises, and that at least one member of the flight staff, such as the head flight attendant, be trained and certified in the indications for and techniques of their use.</p> <p>(Res. 415, A-04; Reaffirmed: CSAPH Rep. 1, A-14)</p>	
<p>H-440.899</p>	<p>Immunization Registries</p>	<p>Our AMA encourages: (1) physicians to participate in the development of immunization registries in their communities and use them in their practices for patients of all ages; (2) electronic health record (EHR) vendors to add features to automate the exchange of vaccination information in the patient EHR to state immunization registries to improve and help ensure completeness and accuracy of vaccination records. EHR vendors and registry administrators need to work with physicians and other health professionals to facilitate the exchange of needed vaccination information by establishing seamless, bidirectional communication capabilities for physicians, other vaccine providers, and immunization registries; and (3) all states to move rapidly to provide comprehensive lifespan immunization registries that are interfaced with other state registries.</p> <p>(Res. 415, A-99; Reaffirmed: 415, A-01; Reaffirmation A-09; Modified: CSAPH Rep. 4, I-14)</p>	<p>Retain; still relevant.</p>
<p>H-440.919</p>	<p>Toward the Control of E. Coli Infection</p>	<p>The AMA: (1) urges physicians to: (a) familiarize themselves with infection due to E. coli 0157:H7; (b) regularly request culture for this organism in any study of infection associated with bloody diarrheal stools; and (c) expand efforts to educate consumers, food processors, and food handlers about the general importance of proper food handling and preparation; and (2) encourages and supports the continuing efforts of the FDA, and of the U.S. Department of Agriculture and its Food Safety and Inspection Service, to develop new and improved methods and technologies for reducing or eliminating bacterial contamination of meat and meat products for human consumption.</p> <p>(Sub. Res. 509, I-94; Reaffirmed and Modified: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)</p>	<p>Retain; still relevant.</p>
<p>H-440.922</p>	<p>Gambling Can Become Compulsive Behavior</p>	<p>The AMA: (1) encourages physicians to advise their patients of the addictive potential of gambling; (2) encourages states which operate gambling programs to provide a fixed percentage of their revenue for education, prevention and treatment of gambling compulsive behavior disorder; and (3) requests that states which operate</p>	<p>Retain as amended to reflect updated language of the DSM-5-TR, which refers to “gambling disorder.”</p>

		<p>gambling programs affix to all lottery tickets and display at all lottery counters a sign which states that gambling <u>disorder</u> may become a compulsive behavior and help is available through your local gambling hotline. (Res. 430, A-94; Reaffirmed: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)</p>	
<p>H-440.938</p>	<p>Multiple-Drug Resistant Tuberculosis - A Multifaceted Problem</p>	<p>(1) Testing <u>Screening</u> for tuberculous infection should be performed routinely on all HIV-infected patients, according to current recommendations from the <u>CDC U.S. Public Health Service</u>. (2) Testing for HIV infection should be routinely performed on all <u>Routine HIV testing is recommended for persons with active tuberculosis.</u> (3) Reporting of HIV infection and tuberculosis should be linked to enhance appropriate medical management and epidemiologic surveillance. (43) Aggressive contact tracing should be pursued for cases of active tuberculosis, especially if HIV-infected contacts or multiple-drug resistant tuberculosis strains have been involved. (54) HIV-infected health care workers and their physicians must be aware of the high risk of clinical TB for persons whose immune systems are compromised, due to HIV or other causes. They should be carefully apprised of their risk, and the risks and benefits of their caring for persons with active TB or suspected TB should be carefully considered. (65) HIV-infected and other immunocompromised patients should be sufficiently separated from tuberculosis patients and the air they breathe so that transmission of infection is unlikely. (76) All health care workers should have a tuberculin skin test upon employment, with the frequency of retesting determined by the prevalence of the disease in the community in <u>accordance with CDC recommendations</u>. Individuals with a positive skin test should be evaluated and managed according to current public health service recommendations. (87) Health care facilities that treat patients with tuberculosis should rigorously adhere to published public health service <u>CDC guidelines</u> for preventing the nosocomial transmission of tuberculosis. (98) Adequate and safe facilities must be available for the care of patients with tuberculosis; in some areas this may necessitate the establishment of sanitariums or other regional centers of excellence in tuberculosis treatment. (109) Clinical tuberculosis laboratories should develop the capability of reliably performing or having reliably performed for them rapid identification and drug susceptibility tests for tuberculosis.</p>	<p>Retain as amended. Updated terminology for accuracy, including reference of appropriate federal agency.</p>

		<p>(4110) Routinely, drug susceptibility tests should be performed on isolates from patients with active tuberculosis as soon as possible.</p> <p>(4211) A program of directly observed therapy for tuberculosis <u>is a standard of care</u> should be implemented when patient compliance is a problem.</p> <p>(4312) The AMA should enlist the aid of the Pharmaceutical Research and Manufacturers of America (PhRMA) in encouraging manufacturers to develop new drugs and vaccines for tuberculosis.</p> <p>(4413) The federal government should increase funding significantly for tuberculosis control and research to curtail the further spread of tuberculosis and encourage development of new and effective diagnostics, drug therapies, and vaccines.</p> <p>(4514) The special attention of physicians, public health authorities, and funding sources should be directed toward high risk and high incidence populations such as the homeless, immigrants, minorities, health care workers in high risk environments, prisoners, children, adolescents, and pregnant people <u>women</u>.</p> <p>(4615) The AMA will develop educational materials for physicians that will include but not be limited to the subtleties of testing for TB in HIV-infected individuals; potential risk to HIV-infected individuals exposed to infectious diseases, including TB; and other issues identified in this report.</p> <p>(4716) The AMA encourages physicians to remain informed about advances in the treatment of tuberculosis, including the availability of combination forms of drugs, that may reduce the emergence of drug-resistant strains. (BOT Rep. OO, A-92; Sub. Res. 505, I-94; Reaffirmed and Modified: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)</p>	
<p>H-440.942</p>	<p>State Health Officer Report at Annual Meeting of State Medical Society Meetings</p>	<p>The AMA urges each state medical society to extend to their respective state health officer a standing invitation to participate in and report to the annual meeting of their house of delegates upon issues, accomplishments, problems, and needs of public health significance within the state. (Res. 429, I-91; Reaffirmed by Res. 417, I-94; Reaffirmed: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)</p>	<p>Retain; still relevant.</p>
<p>H-45.976</p>	<p>Drug and Alcohol Use in Aviation</p>	<p>1. Our AMA urges the FAA to establish programs for personnel involved in all facets of aviation that reduce the impact of drug and alcohol use in order to further aviation safety.</p> <p>2. Our AMA encourages continued studies by the Federal Aviation Administration of problems in the use of alcohol by pilots in general aviation and flight crews of commercial airlines.</p>	<p>Retain; still relevant.</p>

		(CCB/CLRPD Rep. 3, A-14)	
H-460.901	Genomics in Hypertension: Risk Prediction and Treatment	Our AMA encourages continued research on the genetic control of blood pressure, including in pediatric populations, and the development of genomic-based tools that may assist health professionals in better predicting risk and targeting therapy for hypertension, and supports the view that hypertension clinical trial designs should attempt to reduce phenotypic heterogeneity in order to improve the quality and interpretation of results. (CSAPH Rep. 1, I-14)	Retain; still relevant.
H-460.938	Effects of Electric and Magnetic Fields	The AMA: (1) will continue to monitor developments and issues related to the effects of electric and magnetic fields, even though no scientifically documented health risk has been associated with the usually occurring levels of electromagnetic fields; (2) encourages research efforts sponsored by agencies such as the National Institutes of Health, U.S. Department of Energy, and the National Science Foundation to continue on exposures to electromagnetic fields and their effects, average public exposures, occupational exposures, and the effects of field surges and harmonics; and (3) supports broad dissemination of findings and recommendations of authoritative, multidisciplinary committees, such as those convened under the auspices of the National Academy of Sciences, National Council on Radiation Protection, International Agency for Research on Cancer, and the National Institute for Environmental Health Sciences. (CSA Rep. 7 - I-94; Reaffirmed and Modified: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Retain; still relevant.
H-460.940	Support for Federal Funding of Early-Stage Embryo Research	The AMA supports federal funding of biomedical research which promises significant human and scientific benefits. (Res. 242, I-94; Reaffirmed: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Retain; still relevant.
H-460.988	Need for Continued Use of Animals in Research and Education	The AMA supports (1) the humane use of animals essential to research, education and the development of drugs and medical devices; and (2) efforts to assure the availability of animals for these purposes. (Res. 140, A-84; Reaffirmed by CLRPD Rep. 3 - I-94; Reaffirmed and Modified: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Retain; still relevant.
H-480.949	Nanotechnology, Safety and Regulation	Our AMA: (1) recognizes the benefits and potential risks of nanotechnology; (2) supports responsible regulation of nanomaterial products and applications to protect the public's health and the environment; and (3) encourages continued study on the health and environmental effects of exposure to nanomaterials.	Retain; still relevant.

		(CSAPH Rep. 2, A-13; Reaffirmed in lieu of Res. 510, A-14)	
H-480.975	Patents on Medical and Surgical Procedures	The AMA condemns the patenting of medical and surgical procedures and will work with Congress to outlaw this practice. (Sub. Res. 2, A-94; Reaffirmed: BOT Rep. 29, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Retain; still relevant.
H-490.910	Secondhand Smoke	1. Our AMA urges the President of the United States to issue an Executive Order making all federal workplaces, including buildings and campuses, entirely smoke free and urges its federation members to do the same. 2. Our AMA supports legislation that prohibits smoking while operating or riding in a vehicle that contains children. (Res. 417, A-09; Appended: Res. 202, A-14)	Retain; still relevant.
H-490.912	Tobacco as an Incentive in Behavior Modification Programs	The AMA condemns the use of tobacco as an incentive in behavior modification programs. (CSA Rep. 3, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Retain; still relevant.
H-490.915	Tobacco Use in Prison Populations	It is the policy of our AMA to (1) recognize and promote the policy that all anti-smoking policies that apply to the general population should apply equally to persons who are incarcerated in local jails, state prisons, and federal prisons; (2) work actively to stop the manufacture of cigarettes by any prison or jail system in the United States; (3) work actively to stop the subsidy of cigarette sales in all jail and prison systems; (4) ensure that the prohibition of smoking by minors be enforced in the correctional system; (5) be committed to smoking cessation programs in correctional facilities and encourage physicians working in correctional systems to include smoking cessation counseling and programs for their patients who smoke; (6) work through its representative to the National Commission on Correctional Health Care to ensure that smoking cessation counseling be made a national standard for correctional medicine; (7) develop model legislation providing for smoke-free prison areas for all inmates, and particularly that common areas including cell blocks and recreation areas not be smoking areas; and (8) support legislation banning smoking in prisons and jails. (CSA Rep. 3, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Retain; still relevant.
H-495.979	Evaluation of the Health Hazards of Clove Cigarettes	AMA's existing policy vigorously opposing the use of any tobacco product is extended to include explicit opposition to the use of clove cigarettes. Further, AMA recognizes that clove cigarette smoking may present an additional hazard to susceptible individuals. (CSA Rep. 3, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Retain; still relevant.

H-495.980	Cigar Smoking	Our AMA will work to have federal and state governments take legal, regulatory, and educational action to protect the public from the ill effects of cigar smoking in a manner similar to those actions taken regarding cigarettes. (CSA Rep. 3, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Retain; still relevant.
H-495.982	Tax-Free Tobacco Products	Our AMA encourages Native American nations to stop selling tax-free tobacco products because of the profound public health implications of the sale of tax-free tobacco products. (CSA Rep. 3, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Retain; still relevant.
H-495.984	Tobacco Advertising and Media	Our AMA: (1) in keeping with its long-standing objective of protecting the health of the public, strongly supports a statutory ban on all advertising and promotion of tobacco products; (2) as an interim step toward a complete ban on tobacco advertising, supports the restriction of tobacco advertising to a "generic" style, which allows only black-and-white advertisements in a standard typeface without cartoons, logos, illustrations, photographs, graphics or other colors; (3) (a) recognizes and condemns the targeting of advertisements for cigarettes and other tobacco products toward children, minorities, and women as representing a serious health hazard; (b) calls for the curtailment of such marketing tactics; and (c) advocates comprehensive legislation to prevent tobacco companies or other companies promoting look-alike products designed to appeal to children from targeting the youth of America with their strategic marketing programs; (4) supports the concept of free advertising space for anti-tobacco public service advertisements and the use of counter-advertising approved by the health community on government-owned property where tobacco ads are posted; (5) (a) supports petitioning appropriate government agencies to exercise their regulatory authority to prohibit advertising that falsely promotes the alleged benefits and pleasures of smoking as well worth the risks to health and life; and (b) supports restrictions on the format and content of tobacco advertising substantially comparable to those that apply by law to prescription drug advertising; (6) publicly commends those publications that have refused to accept cigarette advertisements and supports publishing annually, via JAMA and other appropriate publications, a list of those magazines that have voluntarily chosen to decline tobacco ads, and circulation of a list of those publications to every AMA member; (7) urges physicians to mark the covers of magazines in the waiting area that contain tobacco	Retain; still relevant.

		<p>advertising with a disclaimer saying that the physician does not support the use of any tobacco products and encourages physicians to substitute magazines without tobacco ads for those with tobacco ads in their office reception areas;</p> <p>(8) urges state, county, and specialty societies to discontinue selling or providing mailing lists of their members to magazine subscription companies that offer magazines containing tobacco advertising;</p> <p>(9) encourages state and county medical societies to recognize and express appreciation to any broadcasting company in their area that voluntarily declines to accept tobacco advertising of any kind;</p> <p>(10) urges the 100 most widely circulating newspapers and the 100 most widely circulating magazines in the country that have not already done so to refuse to accept tobacco product advertisements, and continues to support efforts by physicians and the public, including the use of written correspondence, to persuade those media that accept tobacco product advertising to refuse such advertising;</p> <p>(11) (a) supports efforts to ensure that sports promoters stop accepting tobacco companies as sponsors; (b) opposes the practice of using athletes to endorse tobacco products and encourages voluntary cessation of this practice; and (c) opposes the practice of tobacco companies using the names and distinctive hallmarks of well-known organizations and celebrities, such as fashion designers, in marketing their products;</p> <p>(12) will communicate to the organizations that represent professional and amateur sports figures that the use of all tobacco products while performing or coaching in a public athletic event is unacceptable. Tobacco use by role models sabotages the work of physicians, educators, and public health experts who have striven to control the epidemic of tobacco-related disease;</p> <p>(13) (a) encourages the entertainment industry, including movies, videos, and professional sporting events, to stop portraying the use of tobacco products as glamorous and sophisticated and to continue to de-emphasize the role of smoking on television and in the movies; (b) will aggressively lobby appropriate entertainment, sports, and fashion industry executives, the media and related trade associations to cease the use of tobacco products, trademarks and logos in their activities, productions, advertisements, and media accessible to minors; and (c) advocates comprehensive legislation to prevent tobacco companies from targeting the youth of America with their strategic marketing programs; and</p>	
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		<p>(14) encourages the motion picture industry to apply an "R" rating to all new films depicting cigarette smoking and other tobacco use. (CSA Rep. 3, A-04; Appended: Res. 427, A-04; Reaffirmation A-05; Reaffirmation A-14)</p>	
<p>H-500.975</p>	<p>AMA Corporate Policies on Tobacco</p>	<p>(1) Our AMA: (a) continues to urge the federal government to reduce and control the use of tobacco and tobacco products; (b) supports developing an appropriate body for coordinating and centralizing the Association's efforts toward a tobacco-free society; and (c) will defend vigorously all attacks by the tobacco industry on the scientific integrity of AMA publications. (2) It is the policy of our AMA to continue to use appropriate lobbying resources to support programs of anti-tobacco health promotion and advertising. (3) Our AMA's House of Delegates endorses the April 24, 1996, statement by the AMA Secretary-Treasurer that all physicians, health professionals, medical schools, hospitals, public health advocates, and citizens interested in the health and welfare of our children should review their personal and institutional investments and divest of any tobacco holdings (including mutual funds that include tobacco holdings); and specifically calls on all life and health insurance companies and HMOs to divest of any tobacco holdings. (4) Our AMA defines the Tobacco Industry as companies or corporate divisions that directly produce or purchase tobacco for production or market tobacco products, along with their research and lobbying groups, including the Council for Tobacco Research and the Smokeless Tobacco Research Council. A company or corporate division that does not produce or market tobacco products but that has a tobacco producing company as or among its owners will not be considered a prohibited part of the tobacco industry as long as it does not promote or contribute to the promotion, sale and/or use of tobacco products. If such promotional practices begin, the company will be placed on an "unacceptable for support" list. (5) Accordingly, it is the policy of our AMA (a) not to invest in tobacco stocks or accept financial support from the tobacco industry; (b) to urge medical schools and their parent universities to eliminate their investments in corporations that produce or promote the use of tobacco and discourage them from accepting research funding from the tobacco industry; (c) to likewise urge all scientific publications to decline such funded research for publication; and (d) to encourage state and county medical societies and members to divest of any and all tobacco stocks. (6) Our AMA (a) encourages state and local medical societies to determine whether candidates</p>	<p>Retain; still relevant.</p>

		for federal, state and local offices accept gifts or contributions of any kind from the tobacco industry, and publicize their findings to both their members and the public; and (b) urges state and county medical societies and local health professionals along with their allies to support efforts to strengthen state and local laws that require public disclosure of direct and indirect expenditures to influence legislation or ordinances, given recent allegations about tobacco industry strategies. (CSA Rep. 3, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	
H-505.962	Smoking on International Flights	The AMA (1) will join other concerned organizations to seek an FAA ban on smoking on all flights originating from or destined to the U.S.; and (2) in conjunction with the World Health Organization and the World Medical Association, will work with the medical department of the International Civil Aviation Organization to ban smoking on all international flights. (CSA Rep. 3, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Rescind, accomplished. Smoking is banned on international flights.
H-505.963	Federal Efforts Related to Smoking Cessation	Our AMA endorses supports the use of the federally-funded National Tobacco Quitline network and ongoing media campaigns to help Americans quit using tobacco. (CSA Rep. 3, A-04; Modified: CSAPH Rep. 1, A-14)	Retain as amended.
H-55.970	Uniform Cancer Staging	Our AMA (1) supports the tumor, node involvement, metastasis (TNM) system accepted by the American Joint Committee on Cancer and the Union for International Cancer Control for staging of cancer; (2) urges that this system be used in any published articles or information and be included as a requirement in Instructions to Authors; (3) encourages each state association to use this system in any educational forum or scientific meeting which it sponsors; and (4) supports general utilization of the Cancer Staging Manual developed by the American Joint Committee on Cancer. (CCB/CLRPD Rep. 3, A-14)	Retain; still relevant.
H-55.972	Early Detection and Prevention of Skin Cancer	Our AMA: (1) encourages all physicians to (a) perform skin self-examinations and to examine themselves and their families on the first Monday of the month of May, which is designated by the American Academy of Dermatology as Melanoma Monday; (b) examine their patients' skins for the early detection of melanoma and nonmelanoma skin cancer; (c) urge their patients to perform regular self-examinations of their skin and assist their family members in examining areas that may be difficult to examine; and (d) educate their patients concerning the correct way to perform skin self-examination; (2) supports mechanisms for the	Retain; still relevant.

		education of lay professionals, such as hairdressers and barbers, on skin self-examination to encourage early skin cancer referrals to qualified health care professionals; and (3) supports and encourages prevention efforts to increase awareness of skin cancer risks and sun-protective behavior in communities of color. Our AMA will continue to work with the American Academy of Dermatology, National Medical Association and National Hispanic Medical Association and public health organizations to promote education on the importance of skin cancer screening and skin cancer screening in patients of color. (CCB/CLRPD Rep. 3, A-14)	
H-60.923	Meningococcal Vaccination for School Children	Our AMA supports efforts to require that school children receive meningococcal vaccine per <u>as recommended by</u> the Advisory Committee on Immunization Practices guidelines. (Res. 414, A-14)	Retain as amended. The Advisory Committee on Immunization Practices recommends vaccines for use in the population but does not make decisions on school requirements.
H-60.938	Adolescent Sexual Activity	Our AMA (a) endorses the joint position "Protecting Adolescents: Ensuring Access to Care and Reporting Sexual Activity and Abuse"; and (b) supports the following principles for consideration in development of public policy: (i) Sexual activity and sexual abuse are not synonymous and that many adolescents have consensual sexual relationships; (ii) It is critical that adolescents who are sexually active receive appropriate confidential health care and screening; (iii) Open and confidential communication between the health professional and adolescent patient, together with careful clinical assessment, can identify the majority of sexual abuse cases; (iv) Physicians and other health care professionals must know their state laws and report cases of sexual abuse to the proper authority in accordance with those laws, after discussion with the adolescent and/or parent as appropriate; (v) Federal and state laws should support physicians and other health care professionals in their role in providing confidential health care to their adolescent patients; and (vi) Federal and state laws should affirm the authority of physicians and other health care professionals to exercise appropriate clinical judgment in reporting cases of sexual activity. (Res. 825, I-04; Modified: CSAPH Rep. 1, A-14)	Retain as amended to remove language endorsing a specific joint position statement, while retaining the principles.
H-60.979	Physical Activity Guidelines	Our AMA supports the continued expert review and development of national guidelines regarding physical activity for all ages and the dissemination of such guidelines to physicians. (Res. 186, I-90; Reaffirmed: Sunset Report, I-00; Modified: BOT Rep. 10, A-14)	Retain; still relevant.
H-60.996	Missing Children Identification	The AMA supports (1) development of a means of identifying children; and (2) education of the public and parents on the fingerprinting and	Retain; still relevant.

		documentation of characteristic identifying marks as a matter of record, should it be necessary to assist officials in locating a missing child. (Res. 98, A-84; Reaffirmed by CLRPD Rep. 3 - I-94; Reaffirmed: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	
H-75.985	Access to Emergency Contraception	It is the policy of our AMA: (1) that physicians and other health care professionals should be encouraged to play a more active role in providing education about emergency contraception, including access and informed consent issues, by discussing it as part of routine family planning and contraceptive counseling; (2) to enhance efforts to expand access to emergency contraception, including making emergency contraception pills more readily available through pharmacies, hospitals, clinics, emergency rooms, acute care centers, and physicians' offices; (3) to recognize that information about emergency contraception is part of the comprehensive information to be provided as part of the emergency treatment of sexual assault victims <u>and/or survivors</u> ; (4) to support educational programs for physicians and patients regarding treatment options for the emergency treatment of sexual assault victims <u>and/or survivors</u> , including information about emergency contraception; and (5) to encourage writing advance prescriptions for these pills as requested by their patients until the pills are available over-the-counter. (CMS Rep. 1, I-00; Appended: Res. 408, A-02; Modified: Res. 443, A-04; Reaffirmed: CSAPH Rep. 1, A-14)	Retain as amended to reference updated terminology.
H-75.991	Requirements or Incentives by Government for the Use of Long-Acting Contraceptives	(1) Involuntary use of long-acting contraceptives because of child abuse raises serious questions about a person's fundamental right to refuse medical treatment, to be free of cruel and unusual punishment, and to procreate. The state's compelling interest in protecting children from abuse may be served by less intrusive means than imposing contraception on parents who have committed child abuse. The needs of children may be better met by providing close supervision of the parents, appropriate treatment and social services, and foster placement care when necessary. There is not sufficient evidence to demonstrate that long-acting contraceptives are an effective social response to the problem of child abuse. Before long-acting contraceptives could be considered as a response to individual cases of child abuse, the issue would need to be addressed by society broadly. Society must be careful about taking shortcuts to save resources when constitutional rights are involved. (2) Serious questions are raised by plea bargains, or negotiations with child welfare authorities, that	Retain as amended to update terminology.

		<p>result in the use of long-acting contraceptives. Such agreements are made in inherently coercive environments that lack procedural safeguards. In addition, cultural and other biases may influence decisions by the state to seek the use of a long-acting contraceptive.</p> <p>(3) If welfare or other government benefits were based on the use of long-acting contraceptive agents, individuals would be required to assume a potentially serious health risk before receiving their benefits. Government benefits should not be made contingent on the acceptance of a health risk.</p> <p>(4) Individuals should not be denied access to effective contraception because of their <u>inability to pay indigence</u>. Use of long-acting contraceptives should be covered by Medicaid and other health insurance programs, both public and private.</p> <p>(5) Long-acting contraceptives may be medically contraindicated. Assessing the health risks of long-acting contraceptives is substantially outside the purview of courts and legislatures.</p> <p>(BOT Rep. EE, I-91; Reaffirmed: Sunset Report, I-01; Reaffirmation A-04; Reaffirmed: CSAPH Rep. 1, A-14)</p>	
<p>H-80.996</p>	<p>Scientific Status of Refreshing Recollection by the Use of Hypnosis</p>	<p>The AMA believes that (1) With witnesses and victims concerning refreshing recollection, the use of hypnosis should be limited to the investigative process. Specific safeguards should be employed to protect the welfare of the subject and the public, and to provide the kind of record that is essential to evaluate the additional material obtained during and after hypnosis; (2) A psychological assessment of the subject's state of mind should be carried out prior to the induction of hypnosis in an investigative context, and informed consent should be obtained; (3) Hypnosis should be conducted by a skilled psychiatrist or psychologist, who is aware of the legal implications of the use of hypnosis for investigative purposes; a complete taped and/or precise written record of the clinician's prior knowledge of the case must be made; complete videotape recordings of the pre-hypnotic evaluation and history, the hypnotic session, and the post-hypnotic interview, showing both the subject and the hypnotist, should be obtained; (4) Ideally, only the subject and the psychiatrist or psychologist should be present; (5) Some test suggestions of known difficulty should be given to provide information about the subject's ability to respond to hypnosis; (6) The subject's response to the termination of hypnosis and the post-hypnotic discussion of the experience of hypnosis are of major importance in discussing the subject's response; (7) Medical responsibility for the health and welfare of the subject cannot be abrogated by</p>	<p>Retain; still relevant.</p>

		<p>the investigative intent of hypnosis; and (8) Continued research should be encouraged. (CSA Rep. K, I-84; Reaffirmed: CSA Rep. 5, A-94; Reaffirmed by CLRPD Rep. 3 - I-94; Reaffirmed and Modified: CSA Rep. 6, A-04; Reaffirmed: CSAPH Rep. 1, A-14)</p>	
<p>H-85.953</p>	<p>Improving Death Certification Accuracy and Completion</p>	<p>1. Our AMA: (a) acknowledges that the reporting of vital events is an integral part of patient care; (b) urges physicians to ensure completion of all state vital records carefully and thoroughly with special attention to the use of standard nomenclature, using legible writing and accurate diagnoses; and (c) supports notifying state medical societies and state departments of vital statistics of this policy and encouraging their assistance and cooperation in implementing it.</p> <p>2. Our AMA also: (a) supports the position that efforts to improve cause of death statistics are indicated and necessary; (b) endorses the concept that educational efforts to improve death certificates should be focused on physicians, particularly those who take care of patients in facilities where patients are likely to die, namely in acute hospitals, nursing homes and hospices; and (c) supports the concept that training sessions in completion of death certificates should be (i) included in hospital house staff orientation sessions and clinical pathologic conferences; (ii) integrated into continuing medical education presentations; (iii) mandatory in mortality conferences; and (iv) included as part of in-service training programs for nursing homes, hospices and geriatric physicians.</p> <p>3. Our AMA further: (a) promotes and encourages the use of ICD codes among physicians as they complete medical claims, hospital discharge summaries, death certificates, and other documents; (b) supports cooperating with the National Center for Health Statistics (NCHS) in monitoring the four existing models for collecting tobacco-use data; (c) urges the NCHS to identify appropriate definitions, categories, and methods of collecting risk-factor data, including quantification of exposure, for inclusion on the U.S. Standard Certificates, and that subsequent data be appropriately disseminated; and (d) continues to encourage all physicians to report tobacco use, exposure to environmental tobacco smoke, and other risk factors using the current standard death certificate format. (CCB/CLRPD Rep. 3, A-14; Modified: Speakers Rep., A-15)</p>	<p>Retain; still relevant.</p>
<p>H-90.970</p>	<p>Disabled Parking</p>	<p>Our AMA: (1) encourages physicians to become familiar with laws in their states for certifying a patient's need for disabled parking privileges; and (2) supports efforts to educate the public on the appropriate use of parking spaces for the disabled.</p>	<p>Retain; still relevant.</p>

	(CCB/CLRPD Rep. 3, A-14)	
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REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2-A-24

Subject: Comparative Effectiveness Research

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

Referred to: Reference Committee E

1 INTRODUCTION

2

3 American Medical Association (AMA) Policy H-450.922, “Comparative Effectiveness Research,”
4 as adopted at A-23 asked that “our American Medical Association study the feasibility of including
5 comparative effectiveness studies in various FDA drug regulatory processes, including
6 comparisons with existing standard of care, available generics and biosimilars, and drugs
7 commonly used off-label and over-the-counter.” This report serves as the Council on Science and
8 Public Health’s response to this charge.

9

10 METHODS

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12 English language articles were selected from searches of PubMed and Google Scholar using the
13 search terms “comparative effectiveness research” and “comparative effectiveness research AND
14 regulation.” Additional articles were identified by manual review of the reference lists of pertinent
15 publications. Web sites managed by government agencies and applicable organizations were also
16 reviewed for relevant information.

17

18 BACKGROUND

19

20 Comparative effectiveness research (CER) is defined by the National Academy of Medicine as “the
21 generation and synthesis of evidence that compares the benefits and harms of alternative methods
22 to prevent, diagnose, treat, and monitor a clinical condition or to improve the delivery of care.”¹ At
23 the simplest level, CER shifts the clinical research question from “is this safe?” and “does this
24 work?” to “is this better?”. The question posed by the original resolution thus becomes whether the
25 U.S. Food and Drug Administration (FDA) should ask sponsors to prove their new drug (or device)
26 is superior to existing options on the market as a part of the regulatory process – either pre- or post-
27 market approval.

28

29 The AMA has published several previous reports detailing the benefits of CER (including Council
30 on Medical Service (CMS) Report 5-I-16 and CMS Report 4-I-19) and include a thorough list of
31 principles the AMA holds for a federally funded CER entity. Briefly, these reports were focused on
32 the incorporation of value into the pricing of pharmaceuticals, which include utilizing CER to
33 better understand the long-term cost of a treatment compared to its alternatives. As such, this report
34 will focus solely on the use of CER in the regulatory context.

1 DISCUSSION

2
3 *The Authority of the FDA*

4
5 Under the Food, Drug and Cosmetics Act, the FDA assesses new drug applications for two criteria:
6 safety and efficacy.² Within those criteria, however, the FDA commonly assesses new drug
7 applications in the context of the disease state and the drug landscape.³ Per the FDA's Guidance for
8 Industry, the risk-benefit analysis for new drug applications includes the following criteria: (1)
9 analysis of the condition, (2) current treatment options, (3) benefit, and (4) risk and risk
10 management.⁴ A new drug may be known to have serious side effects and toxicity, but if it is used
11 to treat a terminal disease with no currently available treatment, the risk-benefit analysis by the
12 FDA and its advisory committees may support approval. For example, the FDA advisory
13 committee evaluating Trogarzo (ibalizumab-uiyk) for the treatment of multi-drug resistant HIV
14 found that the underlying clinical trial design resulted in difficulty assessing the durability of the
15 drug's effectiveness.⁵ However, given the limited options for this high-need population, the
16 advisory committee found this uncertainty to be tolerable, and ultimately recommended approval.

17
18 Under the current regulatory framework, the most common method to demonstrate efficacy and
19 safety is through placebo-controlled studies. Using this model, researchers seek to prove that their
20 new drug is efficacious by having beneficial outcomes compared to a placebo (passive control). By
21 contrast, a CER approach for medications (or devices) may measure superiority, non-inferiority, or
22 equivalence. CER requires an active control, in which outcomes of the agent are compared to a
23 proven, efficacious treatment rather than being compared to placebo.^{6,7} It should be noted that CER
24 of active control superiority, non-inferiority, and equivalence studies are all routinely utilized by
25 the FDA in approval decisions in the current regulatory framework, most commonly in instances
26 where a placebo-controlled study may be unethical to perform.

27
28 *Re-labeling Generic Drugs*

29
30 CER is commonly used for evaluating the efficacy of off-label applications for drugs, as they may
31 not have placebo-controlled clinical trials supporting off-label use.⁸⁻¹⁰ One of the potential results
32 of CER in this context is that non-inferiority trials may result in the re-labeling of drugs to expand
33 approved indications. For example, lenvatinib (trade name Lenvima) was first granted orphan drug
34 status in 2012 for treating thyroid cancer, but later had its approved indications revised by the FDA
35 to include first-line treatment of unresectable hepatocellular carcinoma after a non-inferiority trial
36 was performed comparing lenvatinib and sorafenib.¹¹

37
38 The issue, however, comes down to which drugs are selected for evaluation and ultimately
39 submitted for re-labeling. In the instance of lenvatinib, which is still under patent, the non-
40 inferiority trial was sponsored by the patent holder and pharmaceutical company, Eisai.¹² Seeking
41 labeling changes for off patent products, like generic medicines or medical devices, with no
42 industry sponsor is much rarer due to the lack of financial incentive. One example of the
43 difficulties in updating the labeling for a generic medicine is metformin, a first-line treatment for
44 type 2 diabetes. In this instance, concerns over elevated rates of lactic acidosis resulted in the initial
45 1994 labeling having a contraindication of metformin in patients with elevated creatine levels.¹³ By
46 the mid-2000s, however, evidence suggested that this adverse event was rare, and lactic acidosis
47 incidence rates in patients with diabetes receiving metformin were similar to those not receiving
48 metformin.¹⁴ Despite this evidence, it took four years and two citizen petitions by a group of
49 physician experts and academic partners to get partial updates to the labeling of metformin.¹³ Given
50 the additional level of effort and advocacy required, using research (CER or otherwise) to inform
51 updates in labeling of generic drugs is exceedingly rare and burdensome.

1 The AMA vigorously supports the physician's ability to exercise clinical judgement and prescribe
2 medications off-label, yet the inclusion (or exclusion) of indications and contraindications in the
3 FDA labeling can have significant ramifications on clinical uptake of medications and coverage by
4 insurers.¹⁵⁻¹⁸

6 *Novel Drug Submissions*

8 Perhaps more nuanced is the potential role of CER in new drug applications and approvals, and
9 whether the FDA should consider if a new drug is superior to what already exists on the market
10 before granting approval. Proponents argue that this approach has multiple benefits to the system,
11 gives patients and physicians a better understanding of which medications to prioritize in treatment
12 plans, incentivizes research into understudied diseases, disincentivizes advertising which conflates
13 newness with effectiveness, and reduces the financial burden on government entities to fund post-
14 market CER trials.¹⁹

16 A common example of how CER could have been used in the approvals process is the case of
17 esketamine. Ketamine, which was originally approved by the FDA for as an anesthetic in 1970, has
18 received attention for use in treatment-resistant depression (TRD).²⁰ Under normal chemical
19 synthesis conditions, ketamine is made up of a 50:50 mixture of the enantiomers (R)-ketamine and
20 (S)-ketamine (also known as esketamine). In 2019, Janssen received FDA approval for a nasal
21 spray for TRD treatment that comprised of pure esketamine (i.e., no (R)-ketamine), under the trade
22 name Spravato.²¹ Esketamine was approved for TRD utilizing a placebo-controlled study, in which
23 esketamine performance was found to be effective compared to placebo.^{22,23}

25 Since its approval, however, esketamine has not been found to be superior to ketamine.²⁴ What is
26 different, though, is their price. Esketamine is an on-patent medication, and as such was estimated
27 by the Institute for Clinical and Economic Review to cost approximately \$39,000/year compared to
28 \$5,300/year for generic ketamine.²⁵ However, due to other factors such as insurance reimbursement
29 and manufacturer rebates, some studies found that patients may pay less out-of-pocket for
30 esketamine, thus driving them towards the product which generates the most profit for the
31 pharmaceutical company.²⁶

33 However, this is ultimately not an issue for the FDA to adjudicate. Deviation from the FDA's role
34 of evaluating "is it safe?" and "is it effective?" would be a radical expansion of scope and would
35 likely endanger the ability for new medications to enter the market. As described above, the FDA
36 already evaluates new drugs or devices within the context of available treatments and the severity
37 of the disease.

39 Instead, the case of esketamine/ketamine further highlights the importance of AMA's advocacy
40 efforts to make sure patients have access and insurance coverage to all medications that are deemed
41 appropriate by their physician, whether they are prescribed for off-label indications or not.
42 Esketamine and ketamine, while similar, have different administration routes and side effect
43 profiles. As such, having both available in the physician's toolbox allows for the patient-physician
44 relationship to be the guide to the treatment plan.

46 Additionally, "is it better?" may be a difficult bar to quantify, particularly for use cases with high
47 levels of heterogeneity. For example, the addition of a zipper to a new medical device may not
48 directly result in improved outcomes for patients, but a physician may appreciate the option. There
49 are also questions as to for *whom* these new medications or devices need to be better. As noted
50 above, esketamine may be more accessible for individuals who are averse to needles or otherwise

1 unable to receive an infusion. Similarly, a new device may make modifications to allow for easier
2 implantation by a physician with a dexterity impairment, but not impact patient care. It is unclear
3 how CER could effectively capture these important use-cases in which innovation and choice is
4 beneficial, but not measurable by clinical outcomes.

5
6 Finally, a requirement to prove that new medicines are better than current options may
7 inadvertently isolate patient populations and make health inequities harder to overcome. For
8 example, clopidogrel is an anti-platelet medicine commonly used for reducing the risk of stroke
9 and heart attack. It is available as a generic medicine, taken orally, and is cheap, highly effective,
10 and well-studied.²⁷ As such, it may be difficult for any new competing medication to become
11 approved if it were required to prove superiority to clopidogrel, placing some patients at a
12 disadvantage. Alternatives to clopidogrel are incredibly important to individuals with CYP2C19
13 genetic mutations, which can make them either hyper- or hypo-metabolizers of clopidogrel,
14 leading to reduced efficacy or increased side effects, respectively.²⁸ CYP2C19 mutations are more
15 prevalent in individuals of Asian and African ancestry.²⁹

16
17 The pharmacogenomic response to clopidogrel is well-known and has resulted in an FDA black
18 box warning on its label.³⁰ As such, one could imagine that CER for the purposes of a clopidogrel
19 alternative could instead focus on its performance in relevant CYP2C19 genotypes. But this
20 difference in response was not always known (the black box warning was added 13 years after
21 approval), and there are likely an incalculable number of genetic mutations that influence drug
22 interactions that are yet to be known and considered in prospective CER.

23 24 CURRENT AMA POLICY

25
26 As described above, the AMA has a long history of supporting off-label prescribing and
27 reimbursement. Per Policy H-120.988, “Patient Access to Treatments Prescribed by Their
28 Physicians,” “[o]ur AMA confirms its strong support for the autonomous clinical decision-making
29 authority of a physician and that a physician may lawfully use an FDA approved drug product or
30 medical device for an off-label indication when such use is based upon sound scientific evidence or
31 sound medical opinion; and affirms the position that, when the prescription of a drug or use of a
32 device represents safe and effective therapy, third party payers, including Medicare, should
33 consider the intervention as clinically appropriate medical care, irrespective of labeling, should
34 fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover
35 appropriate 'off-label' uses of drugs on their formulary.”

36
37 Additionally, per Policy H-460.909, “Comparative Effectiveness Research,” the AMA broadly
38 supports well-funded, scientifically rigorous CER entities, with two highlighted principles: “[t]he
39 CER entity must not have a role in making or recommending coverage or payment decisions for
40 payers,” and “[p]hysician discretion in the treatment of individual patients remains central to the
41 practice of medicine. CER evidence cannot adequately address the wide array of patients with their
42 unique clinical characteristics, co-morbidities and certain genetic characteristics. In addition,
43 patient autonomy and choice may play a significant role in both CER findings and
44 diagnostic/treatment planning in the clinical setting.”

45 46 CONCLUSION

47
48 Comparative effectiveness research is a critical tool for helping physicians give patients the highest
49 quality, most affordable care possible. However, it may not be the most effective tool for
50 determining what drugs should be available on the market. Instead of using CER as a regulatory

1 requirement, it is likely better suited to be used as a tool for bringing affordable, effective
2 medications to patients.

3

4 RECOMMENDATIONS

5

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

8

9 (1) That policy H-450.922, “Comparative Effectiveness Research” be amended by deletion to
10 read as follows:

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12

Our AMA will:

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~~(1) study the feasibility of including comparative effectiveness studies in various FDA drug regulatory processes, including comparisons with existing standard of care, available generics and biosimilars, and drugs commonly used off-label and over-the-counter; and~~
~~(2)~~~~(1) ask the National Institutes of Health to support and fund comparative effectiveness research for approved drugs, including comparisons with existing standard of care, available generics and biosimilars, and drugs commonly used off-label and over-the-counter. (Amend HOD Policy)~~

(2) That policies H-120.988, “Patient Access to Treatments Prescribed by Their Physicians”, and H-460.909, “Comparative Effectiveness Research” be reaffirmed. (Reaffirm HOD Policy)

Fiscal note: less than \$1,000

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APPENDIX

RELEVANT AMA POLICY

Patient Access to Treatments Prescribed by Their Physicians H-120.988

1. Our AMA confirms its strong support for the autonomous clinical decision-making authority of a physician and that a physician may lawfully use an FDA approved drug product or medical device for an off-label indication when such use is based upon sound scientific evidence or sound medical opinion; and affirms the position that, when the prescription of a drug or use of a device represents safe and effective therapy, third party payers, including Medicare, should consider the intervention as clinically appropriate medical care, irrespective of labeling, should fulfill their obligation to their beneficiaries by covering such therapy, and be required to cover appropriate 'off-label' uses of drugs on their formulary.
2. Our AMA strongly supports the important need for physicians to have access to accurate and unbiased information about off-label uses of drugs and devices, while ensuring that manufacturer-sponsored promotions remain under FDA regulation.
3. Our AMA supports the dissemination of generally available information about off-label uses by manufacturers to physicians. Such information should be independently derived, peer reviewed, scientifically sound, and truthful and not misleading. The information should be provided in its entirety, not be edited or altered by the manufacturer, and be clearly distinguished and not appended to manufacturer-sponsored materials. Such information may comprise journal articles, books, book chapters, or clinical practice guidelines. Books or book chapters should not focus on any particular drug. Dissemination of information by manufacturers to physicians about off-label uses should be accompanied by the approved product labeling and disclosures regarding the lack of FDA approval for such uses, and disclosure of the source of any financial support or author financial conflicts.
4. Physicians have the responsibility to interpret and put into context information received from any source, including pharmaceutical manufacturers, before making clinical decisions (e.g., prescribing a drug for an off-label use).
5. Our AMA strongly supports the addition to FDA-approved labeling those uses of drugs for which safety and efficacy have been demonstrated.
6. Our AMA supports the continued authorization, implementation, and coordination of the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act.

Comparative Effectiveness Research D-460.973

Our AMA will solicit from our members and others articles or postings about current clinical topics where comparative effectiveness research should be conducted and will periodically invite AMA members to recommend topics where the need for comparative effectiveness research is most pressing, and the results will be forwarded to the Patient-Centered Outcomes Research Institute (PCORI) once it is established, or to another relevant federal agency.

Res. 221, A-11. Reaffirmed: BOT Rep. 7, A-21

Comparative Effectiveness Research H-460.909

The following Principles for Creating a Centralized Comparative Effectiveness Research Entity are the official policy of our AMA:

PRINCIPLES FOR CREATING A CENTRALIZED COMPARATIVE EFFECTIVENESS RESEARCH ENTITY:

- A. Value. Value can be thought of as the best balance between benefits and costs, and better value as improved clinical outcomes, quality, and/or patient satisfaction per dollar spent. Improving value in the US health care system will require both clinical and cost information. Quality comparative clinical effectiveness research (CER) will improve health care value by enhancing physician clinical judgment and fostering the delivery of patient-centered care.
- B. Independence. A federally sponsored CER entity should be an objective, independent authority that produces valid, scientifically rigorous research.
- C. Stable Funding. The entity should have secure and sufficient funding in order to maintain the necessary infrastructure and resources to produce quality CER. Funding source(s) must safeguard the independence of a federally sponsored CER entity.
- D. Rigorous Scientifically Sound Methodology. CER should be conducted using rigorous scientific methods to ensure that conclusions from such research are evidence-based and valid for the population studied. The primary responsibility for the conduct of CER and selection of CER methodologies must rest with physicians and researchers.
- E. Transparent Process. The processes for setting research priorities, establishing accepted methodologies, selecting researchers or research organizations, and disseminating findings must be transparent and provide physicians and researchers a central and significant role.
- F. Significant Patient and Physician Oversight Role. The oversight body of the CER entity must provide patients, physicians (MD, DO), including clinical practice physicians, and independent scientific researchers with substantial representation and a central decision-making role(s). Both physicians and patients are uniquely motivated to provide/receive quality care while maximizing value.

G. Conflicts of Interest Disclosed and Minimized. All conflicts of interest must be disclosed and safeguards developed to minimize actual, potential and perceived conflicts of interest to ensure that stakeholders with such conflicts of interest do not undermine the integrity and legitimacy of the research findings and conclusions.

H. Scope of Research. CER should include long term and short term assessments of diagnostic and treatment modalities for a given disease or condition in a defined population of patients. Diagnostic and treatment modalities should include drugs, biologics, imaging and laboratory tests, medical devices, health services, or combinations. It should not be limited to new treatments. In addition, the findings should be re-evaluated periodically, as needed, based on the development of new alternatives and the emergence of new safety or efficacy data. The priority areas of CER should be on high volume, high cost diagnosis, treatment, and health services for which there is significant variation in practice. Research priorities and methodology should factor in any systematic variations in disease prevalence or response across groups by race, ethnicity, gender, age, geography, and economic status.

I. Dissemination of Research. The CER entity must work with health care professionals and health care professional organizations to effectively disseminate the results in a timely manner by significantly expanding dissemination capacity and intensifying efforts to communicate to physicians utilizing a variety of strategies and methods. All research findings must be readily and easily accessible to physicians as well as the public without limits imposed by the federally supported CER entity. The highest priority should be placed on targeting health care professionals and their organizations to ensure rapid dissemination to those who develop diagnostic and treatment plans.

J. Coverage and Payment. The CER entity must not have a role in making or recommending coverage or payment decisions for payers.

K. Patient Variation and Physician Discretion. Physician discretion in the treatment of individual patients remains central to the practice of medicine. CER evidence cannot adequately address the wide array of patients with their unique clinical characteristics, co-morbidities and certain genetic characteristics. In addition, patient autonomy and choice may play a significant role in both CER findings and diagnostic/treatment planning in the clinical setting. As a result, sufficient information should be made available on the limitations and exceptions of CER studies so that physicians who are making individualized treatment plans will be able to differentiate patients to whom the study findings apply from those for whom the study is not representative.

CMS Rep. 5, I-08. Reaffirmed: Res. 203, I-09. Reaffirmation I-10. Reaffirmed: CMS Rep. 05, I-16. Reaffirmed: CMS Rep. 4, I-19.

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 4-A-24

Subject: Sex and Gender Differences in Medical Research

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

Referred to: Reference Committee E

1 INTRODUCTION

2
3 At the 2023 Annual meeting of the American Medical Association (AMA's) House of Delegates,
4 subclause 7 of Resolution 004 was referred. It stated that "[our AMA encourage] the [U.S. Food
5 and Drug Administration (FDA)] to internally develop criteria for identifying medication and
6 medical devices seeking FDA approval that were developed based on research that did not include
7 adequate participation of women, and sexual and gender minorities [SGM]." Testimony at the
8 meeting cited concern with this being too prescriptive of an approach for the AMA to take with the
9 FDA on this topic. This report serves as the Council on Science and Public Health's response.

11 METHODS

12
13 English language articles were selected from searches of PubMed and Google Scholar using the
14 search terms "gender bias AND clinical trials", "sex bias AND clinical trials", "gender differences
15 AND adverse events", and "sex differences AND adverse events". Additional articles were
16 identified by manual review of the reference lists of pertinent publications. Web sites managed by
17 government agencies and applicable organizations were also reviewed for relevant information.

19 BACKGROUND

20
21 There has been a long and unfortunately exclusionary history for women, and sex and gender
22 minorities (SGM) participating in clinical trials. Women participating in clinical trials became a
23 topic of intense discussion in the United States and Europe after the tragic discovery of birth
24 defects caused by thalidomide in the 1950s.¹ In response, Congress passed the Kefauver-Harris
25 amendment to the Food, Drug, and Cosmetics Act in 1962 which dramatically expanded the role of
26 the FDA beyond evaluating safety, but also effectiveness, resulting in the modern phased clinical
27 trial model we know today.² By 1977, however, fears of another teratogen like thalidomide resulted
28 in the FDA introducing regulations which functionally barred all women "of child-bearing age"
29 from participating in clinical trials outside of life-saving drugs.³

30
31 After these regulations, the scientific community quickly recognized the impact that excluding
32 women from clinical trials had on health equity, including a call from the U.S. Public Health
33 Service Task Force on Women's Health to improve women's participation in clinical trials.⁴ In
34 1993, the FDA repealed their 1977 rule, and Congress passed a mandate that all studies funded by
35 the National Institute of Health (NIH) include women and assess differences amongst sexes.^{5,6}

36
37 However, despite the changes in the regulatory environment, inequities in clinical trial participation
38 and outcomes persist. These inequities have previously been studied in detail by the Council, and

1 can be found in the 2016 report “An Expanded Definition of Women’s Health.”⁷ This report
2 outlined the ways in which health differences experienced by women are not just associated with
3 reproductive health, and includes biological and socioeconomic factors that impact the risk and
4 severity of conditions such as cardiovascular disease, autoimmune disease, Alzheimer’s disease,
5 and substance use disorders. Further, women’s participation in research (both as participants and as
6 investigators), was discussed, including the lack of female animals used in preclinical research
7 impacting the ability to predict pharmacokinetic or pharmacodynamic differences using biologic
8 sex as a variable.

9
10 Briefly, examination of clinical trials find that enrollment of women is still lower than expected –
11 for example, in 740 clinical trials for cardiovascular disease (N = 862,652 adults), only 38 percent
12 were women.⁸ This trend is also observed across disease state, including psychiatric conditions and
13 cancer.⁹

14
15 Reasons for this gap are multi-factorial, and include concerns related to side effects, impact on
16 fertility, lack of women researchers, and the inability to take time for multiple site visits.¹⁰ At the
17 request of Congress, the National Academy of Sciences, Engineering, and Mathematics released a
18 2022 consensus study towards building equity in women and underrepresented groups in
19 research.¹¹ In its recommendations, the report recommends a variety of strategies: starting with
20 intention, establishing a foundation of trust, being proactive about removing barriers, being
21 flexible, maintaining a strong network of interested groups, being cognizant of social and
22 professional expectations, working in a representative team, and prioritizing resources for equity.

23
24 Participation of SGM in clinical trials is even less representative of the population. SGM, which
25 may include individuals identifying as gay, lesbian, transgender, gender non-binary, or gender
26 expansive, have historically been omitted entirely as a category for clinical research, even when
27 they are a high-risk population. For example, surveys have found that individuals identifying as
28 gay or lesbian have an approximately 61 percent prevalence of a substance use disorder compared
29 to 24 percent for individuals identifying as heterosexual.¹² Yet despite the higher risk of substance
30 use disorders, one analysis found that typically less than 5 percent of substance use disorder studies
31 from 2007 to 2012 reported sexual orientation as a relevant participant demographic.¹³ Similarly, a
32 review of 764 cancer clinical trials from 1991 to 2017 (N = 462,449 patients) found that no trial
33 reported sexual identity, and only two patients were reported as anything other than male or female
34 – and in those instances, they were listed as the non-actionable categories “not reported” and
35 “unknown.”¹⁴ Despite the lack of recognition in studies, SGM are at higher risk for developing
36 cancers related to human immunodeficiency virus and human papillomavirus, or hormone-
37 dependent cancers such as breast cancer in individuals receiving hormone therapy.^{15,16}

38
39 The lack of participation of women and the lack of even tracking SGM in clinical trials has clear
40 impacts on the care those populations subsequently receive. One commonly cited statistic is that
41 women experience adverse drug reactions (ADRs) approximately twice as often as men, with the
42 underlying reason being that lack of women’s participation in clinical trials has led to poor
43 understanding of the influence of sex on pharmacokinetics.¹⁷ In an analysis of NIH-funded clinical
44 trials performed in 2015, only 26 percent of studies explicitly used sex as a variable in their
45 analysis, 72 percent made no mention of sex at all, and many studies with low enrollment of
46 women still represented their data to suggest that it is generalizable across sexes.¹⁸ For SGM, lack
47 of interest by the research community contributes to the ongoing feelings of invisibility and
48 mistrust of physicians.¹⁹

1 THE REGULATORY RESPONSE

2
3 The originally proposed resolution calls for the FDA to develop criteria for identifying medication
4 and devices which did not adequately include women and SGM in clinical trials. In recent years,
5 there have been several efforts at the FDA to improve diversity in clinical trials, in part driven by
6 the Food and Drug Administration Safety and Innovation Act of 2012 (FDASIA) and the Food and
7 Drug Omnibus Reform Act of 2022 (FDORA).

8
9 Under Section 907 of FDASIA, FDA was tasked with evaluating clinical trial participation based
10 on sex, age, race, and ethnicity. The “Section 907 report” included a 2014 action plan for enhanced
11 collection, and included recommendations on more robust demographic information, training for
12 reviewers to be more scrutinizing of demographic data, and tackling barriers for enrollment for
13 certain subpopulations.²⁰

14
15 Per FDORA, all drug and device sponsors are required to consider racial and ethnic diversity
16 through the use of a Diversity Action Plan, to be submitted at the same time as their study
17 protocol.²¹ These plans require drug and device sponsors to describe their rationale for enrollment,
18 broken down by age, sex, racial, and ethnic characteristics, and a specific plan for how they intend
19 on achieving these goals, including specific outreach. As of this writing (January 2024), the
20 guidance has not been finalized, but it is expected to be public before the AMA 2024 Annual
21 Meeting.

22
23 In August 2023, the FDA released an additional draft Guidance for Industry, “Postmarketing
24 Approaches to Obtain Data on Populations Underrepresented in Clinical Trials for Drugs and
25 Biological Products”, which would allow the FDA to require post-market studies as a condition for
26 approval for drugs or devices which did not have adequately diverse populations in the clinical
27 trials.²² Populations explicitly cited in the guidance include (but are not limited to): race, ethnicity,
28 sex, age, gender identity, disability, pregnancy status, and lactation status. These post-market
29 studies may include single-arm trials, randomized trials, real-world data collection, or pooled
30 studies to assess pharmacokinetics and/or pharmacodynamics in populations understudied in the
31 initial trials.

32
33 Finally, post-market studies do not always need to be conducted by the drug sponsor. While post-
34 approval agreements may be strong incentives for drug sponsors with named drugs to maintain
35 their approval while on-patent, many commonly used drugs that are currently off-patent and
36 available as generics were developed without representative women or SGM participation in their
37 clinical trials. As such, there is a distinct possibility that post-market trial requirements for generic
38 drugs could result in lower cost medications simply leaving the marketplace. In those instances,
39 targeted studies for medications at higher-risk for sex- and gender-specific adverse events may be
40 well-suited for federal or academic entities.

41
42 EXISTING AMA POLICY

43
44 The AMA maintains a plethora of policies seeking to improve equity in both patient outcomes and
45 workforce representation. Specific to this report, the AMA has policy recognizing the differences
46 in health outcomes for women in cardiovascular disease (H-525.975, “Heart Disease in Women”),
47 substance use (H-30.943, “Alcohol Use Disorder and Unhealthy Alcohol Use Among Women”),
48 pharmacological response (D-525.993, “Education on Sex-Based Response to Opioids”), and even
49 pharmaceutical advertising (D-105.996, “Impact of Pharmaceutical Advertising on Women's
50 Health”). The AMA maintains policy specific to the health care needs of other gender identities,
51 including a recognition of the higher risk for cancer in this population (H-160.991, “Health Care

1 Needs of Lesbian, Gay, Bisexual, Transgender and Queer Populations”), and the need for improved
2 gender identity and sexual orientation documentation in medical trials (H-315.967, “Promoting
3 Inclusive Gender, Sex, and Sexual Orientation Options on Medical Documentation”). Additionally,
4 it is the policy of the AMA that the FDA perform regular surveillance of research trial participants,
5 and to adequately fund activities that increase participant diversity in trials (H-460.911, “Increasing
6 Minority, Female, and other Underrepresented Group Participation in Clinical Research”).
7

8 CONCLUSION

9

10 The lack of women and SGM participation in clinical trials has resulted in health inequities.
11 Although it may have started as a well-intentioned response to teratogenic medication adverse
12 events, legislative and regulatory actions have contributed to a drug and device development
13 environment with limited inclusion and information on women and sex and gender minorities.
14 Since the early 1990s, there have been changes to the regulatory landscape and efforts to improve
15 the diversity of the research and development workforce, but progress is slow. The FDA has
16 demonstrated a commitment to improving diversity in clinical trials which should be applauded,
17 supported, and promptly strengthened.
18

19 RECOMMENDATIONS

20

21 The Council on Science and Public Health recommends that the following be adopted and the
22 remainder of the report be filed:
23

24 That policy H-525.988, “Sex and Gender Differences in Medical Research” be amended by
25 addition and deletion to read as follows:

26 Our AMA:

27 (1) reaffirms that gender exclusion in broad medical studies questions the validity of the
28 studies' impact on the health care of society at large;

29 (2) affirms the need to include all genders in studies that involve the health of society at
30 large and publicize its policies;

31 (3) supports increased funding into areas of women's health and sexual and gender
32 minority health research;

33 (4) supports increased research on women's health and sexual and gender minority health
34 and the participation of women and sexual and gender minorities in clinical trials, the
35 results of which will permit development of evidence-based prevention and treatment
36 strategies for all women and sexual and gender minorities from diverse cultural and ethnic
37 groups, geographic locations, and socioeconomic status;

38 (5) recommends that all medical/scientific journal editors require, where appropriate, a sex-
39 based and gender-based analysis of data, even if such
40 comparisons are negative; and

41 (6) recommends that medical and scientific journals diversify their review processes to
42 better represent women and sexual and gender minorities; and

43 (7) supports the FDA's requirement of actionable clinical trial diversity action plans from
44 drug and device sponsors that include women, and sex and gender minorities; and

45 (8) supports the FDA's efforts in conditioning drug and device approvals on post-marketing
46 studies which evaluate the efficacy and safety of those products in women and sex and
47 gender minorities when those groups were not adequately represented in clinical trials; and

48 (9) supports and encourages the National Institute of Health and other grant-making
49 entities to fund post-market research investigating pharmacodynamics and
50 pharmacokinetics for generic drugs that did not adequately enroll women, and sex and

1 gender minorities in their clinical trials, prioritizing instances when those populations
2 represent a significant portion of patients or reported adverse drug events. (Amend HOD
3 Policy)

Fiscal note: less than \$1,000

CITED AMA POLICY

Sex and Gender Differences in Medical Research H-525.988

Our AMA:

- (1) reaffirms that gender exclusion in broad medical studies questions the validity of the studies' impact on the health care of society at large;
- (2) affirms the need to include all genders in studies that involve the health of society at large and publicize its policies;
- (3) supports increased funding into areas of women's health and sexual and gender minority health research;
- (4) supports increased research on women's health and sexual and gender minority health and the participation of women and sexual and gender minorities in clinical trials, the results of which will permit development of evidence-based prevention and treatment strategies for all women and sexual and gender minorities from diverse cultural and ethnic groups, geographic locations, and socioeconomic status;
- (5) recommends that all medical/scientific journal editors require, where appropriate, a sex-based and gender-based analysis of data, even if such comparisons are negative; and
- (6) recommends that medical and scientific journals diversify their review processes to better represent women and sexual and gender minorities.

An Expanded Definition of Women's Health H-525.976

Our AMA recognizes the term "women's health" as inclusive of all health conditions for which there is evidence that women's risks, presentations, and/or responses to treatments are different from those of men, and encourages that evidence-based information regarding the impact of sex and gender be incorporated into medical practice, research, and training.

Inclusion of Women in Clinical Trials H-525.991

Our AMA: (1) encourages the inclusion of women, including pregnant women when appropriate, in all research on human subjects, except in those cases for which it would be scientifically irrational, in numbers sufficient to ensure that results of such research will benefit both men and women alike; (2) supports the National Institutes of Health policy requiring investigators to account for the possible role of sex as a biological variable in vertebrate animal and human studies; and (3) encourages translation of important research results into practice.

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

1. Our AMA advocates that:

a. The Food and Drug Administration (FDA) and National Institutes of Health (NIH) conduct annual surveillance of clinical trials by gender, race, and ethnicity, including consideration of pediatric and elderly populations, to determine if proportionate representation of women and minorities is maintained in terms of enrollment and retention. This surveillance effort should be modeled after National Institute of Health guidelines on the inclusion of women and minority populations. b. The FDA have a page on its web site that details the prevalence of minorities and women in its clinical trials and its efforts to increase their enrollment and participation in this research; and c. Resources be provided to community level agencies that work with those minorities, females, and other underrepresented groups who are not proportionately represented in clinical trials to address issues of lack of access, distrust, and lack of patient awareness of the benefits of trials in their health care. These minorities include Black Individuals/African Americans, Hispanics, Asians/Pacific Islanders/Native Hawaiians, and Native Americans.

2. Our AMA recommends the following activities to the FDA in order to ensure proportionate representation of minorities, females, and other underrepresented groups in clinical trials: a. Increased fiscal support for community outreach programs; e.g., culturally relevant community education, community leaders' support, and listening to community's needs; b. Increased outreach to all physicians to encourage recruitment of patients from underrepresented groups in clinical trials; c. Continued education for all physicians and physicians-in-training on clinical trials, subject recruitment, subject safety, and possible expense reimbursements, and that this education encompass discussion of barriers that currently constrain appropriate recruitment of underrepresented groups and methods for increasing trial accessibility for patients; d. Support for the involvement of minority physicians in the development of partnerships between minority communities and research institutions; and e. Fiscal support for minority, female, and other underrepresented groups recruitment efforts and increasing trial accessibility.

3. Our AMA advocates that specific results of outcomes in all clinical trials, both pre- and post-FDA approval, are to be determined for all subgroups of gender, race and ethnicity, including consideration of pediatric and elderly populations; and that these results are included in publication and/or freely distributed, whether or not subgroup differences exist.

Heart Disease in Women H-525.975

1. Our AMA supports increased awareness and education on preventive measures for heart disease in women and encourages comprehensive care of heart disease in women.

2. Our AMA urges research to address the gaps in knowledge related to coronary pathophysiology and diagnostic, treatment, and interventional strategies for heart disease in women; and to better understand the role of demographic, socioeconomic, and psychological factors in the onset of heart disease in women.

Alcohol Use Disorder and Unhealthy Alcohol Use Among Women H-30.943

The AMA recognizes the prevalence of unhealthy use of alcohol among women, as well as current barriers to diagnosis and treatment. The AMA urges physicians to be alert to the presence of alcohol-related problems among women and to screen all patients for alcohol use disorder and dependence. The AMA encourages physicians to educate women of all ages about their increased risk of damage to the nervous system, liver and heart disease from alcohol and about the effect of alcohol on the developing fetus. The AMA encourages adequate funding for research to explore the nature and extent of alcohol use disorder and unhealthy alcohol use among women, effective treatment modalities for women with alcohol use disorder and unhealthy alcohol use, and variations in alcohol use among ethnic and other subpopulations. The AMA encourages all medical education programs to provide greater coverage on alcohol as a significant source of morbidity and mortality in women.

Education on Sex-Based Response to Opioids D-525.993

Our AMA will include educational materials for physicians regarding sex-based differences in their resources related to the opioid epidemic. These sex-based differences include the perception of pain, the impact of co-morbid conditions, response to opioids, risks for opioid use disorder, issues with access, and outcomes of addiction treatment programs among women.

Impact of Pharmaceutical Advertising on Women's Health D-105.996

1. Our AMA urges the US Food and Drug Administration (FDA) to assure that all direct-to-consumer advertising of pharmaceuticals includes information regarding differing effects and risks between the sexes.
2. Our AMA urges the FDA to assure that advertising of pharmaceuticals to health care professionals includes specifics outlining whether testing of drugs prescribed to both sexes has included sufficient numbers of women to assure safe use in this population and whether such testing has identified needs to modify dosages based on sex.

Health Care Needs of Lesbian, Gay, Bisexual, Transgender and Queer Populations H-160.991

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

Promoting Inclusive Gender, Sex, and Sexual Orientation Options on Medical Documentation H-315.967

Our AMA: (1) supports the voluntary inclusion of a patient's biological sex, current gender identity, sexual orientation, preferred gender pronoun(s), preferred name, and clinically relevant, sex specific anatomy in medical documentation, and related forms, including in electronic health records, in a culturally-sensitive and voluntary manner; (2) will advocate for collection of patient data in medical documentation and in medical research studies, according to current best practices, that is inclusive of sexual orientation, gender identity, and other sexual and gender minority traits for the purposes of research into patient and population health; (3) will research the problems related to the handling of sex and gender

within health information technology (HIT) products and how to best work with vendors so their HIT products treat patients equally and appropriately, regardless of sexual or gender identity; (4) will investigate the use of personal health records to reduce physician burden in maintaining accurate patient information instead of having to query each patient regarding sexual orientation and gender identity at each encounter; and (5) will advocate for the incorporation of recommended best practices into electronic health records and other HIT products at no additional cost to physicians.

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REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 5-A-24

Subject: Biosimilar/Interchangeable Terminology

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

Referred to: Reference Committee E

1 INTRODUCTION

2
3 Resolution 245-A-23, which was referred by the American Medical Association’s (AMA) House of
4 Delegates, stated as follows:

5
6 That our American Medical Association repeal policy H-125.976, Biosimilar
7 Interchangeability Pathway (Rescind HOD Policy);

8
9 That our AMA advocate for state and federal laws and regulations that support
10 patient and physician choice of biosimilars and remove the “interchangeable”
11 designation from the FDA’s regulatory framework. (Directive to Take Action)

12
13 This report serves as the Council on Science and Public Health’s findings and recommendations
14 after review of the evidence surrounding the “interchangeable” designation for biosimilar
15 medications.

16
17 METHODS

18
19 English language articles were selected from searches of PubMed and Google Scholar using the
20 search terms “biosimilar AND interchangeable.” Additional articles were identified by manual
21 review of the reference lists of pertinent publications. Web sites managed by government agencies
22 and applicable organizations were also reviewed for relevant information.

23
24 BACKGROUND

25
26 This report deals with several technical terms, including discussion as to how they overlap and
27 differ. As such, definitions are provided in Appendix 1 of this report for the following terms:
28 biologic drug, small molecule drug, generic drug, biosimilar, and interchangeable.

29
30 Biosimilars are a classification of biologic medical products (such as recombinant proteins and
31 gene therapies) which are nearly identical to an existing U.S. Food Drug and Administration (FDA)
32 -approved biologic medicine (called the reference product or innovator product). In that sense, they
33 are often thought of as the equivalent to the “generic” designation for small-molecule drugs,
34 however they have several key differences which will be discussed later in this report.

35 Biosimilars are a relatively new class of large molecule medication, with the first follow-on (i.e., a
36 new medication approved in an already established drug class) protein, Omnitrope (somatotropin),

1 not receiving FDA approval until 2005.¹ However, the FDA has not had a dedicated regulatory
2 pathway for approving biosimilars until passage of the Patient Protection and Affordable Care Act
3 of 2010, which resulted in the first true biosimilar being approved in 2015, when the leukocyte
4 growth factor Zarxio (filgrastim-sndz) was deemed to be biosimilar to Neupogen (filgrastim).² As
5 of December 2023, there have been 45 biosimilars approved by the FDA, including products such
6 as biosimilars for Humira (adalimumab), Avastin (bevacizumab), and Lantus (insulin glargine).

7
8 Biosimilars have a unique naming convention compared to other classes of drugs. First, all biologic
9 drugs are branded, even if they are a biosimilar. To distinguish between two biologic products, a 4-
10 letter suffix is added to the non-proprietary name. For example, filgrastim is a recombinant form of
11 granulocyte colony-stimulating factor. The first biologic drug product in this class was produced by
12 Amgen under the trade name Neupogen (filgrastim). Once Neupogen lost its market exclusivity,
13 biosimilars such as Zarxio (filgrastim-sndz), Nivestym (filgrastim-aafi), and Releuko (filgrastim-
14 ayow) were approved by the FDA. These were all found by the FDA to have similar efficacy and
15 function to Neupogen but have their own brand name and suffix. This naming strategy is intended
16 to convey that biosimilars such as Zarxio and Nivestym are *similar*, but not identical to Neupogen,
17 and allows for easier pharmacovigilance in the event that those differences result in adverse event
18 profile differences. For biologic drugs approved after March 23, 2020, the originator product also
19 contains a 4-letter suffix.

20
21 Similar to the generic drug market, approvals of biosimilars are generally thought to lead to
22 increased access and lower costs for expensive medications on the market. Per one analysis from
23 2016 (before nearly all biosimilars entered the market) biologic drugs comprised less than one
24 percent of prescriptions in the United States, but accounted for over 28 percent of drug
25 expenditures.³ Since then, one study estimates that biosimilars saved patients \$56 billion in
26 medication spending, and account for approximately 60 percent of a given biologic drug's sales
27 volume when biosimilar competition exists.⁴ It should be noted, however, that the introduction of a
28 biosimilar is not a guaranteed method for reducing cost and increasing access – somatropin, the
29 first biologic drug to have a biosimilar approved, has actually had a nearly 20 percent increase in
30 the reference product unit price since the introduction of follow-on competition, even though the
31 follow-on product is markedly cheaper.⁵

32 33 *Distinctions with Generic Drugs*

34
35 As described above, many often think of biosimilars as the “generic drug” version of biologic
36 medicines. However, there are several key differences, which are also summarized in Appendix 2.⁶
37 The first major distinction between biosimilar large molecule drugs and generic small molecules
38 drugs is the complexity of the underlying medicine. Small molecule drugs generally consist of
39 relatively simple organic chemical structures with atom counts on the scale of 10s, and atomic
40 weights on the scale of 100s of Daltons (Da). For example, acetylsalicylic acid (aspirin) has the
41 chemical formula of C₉H₈O₄ (21 total atoms), and a molecular weight of 180 Da. Biologic drugs,
42 by comparison, typically consist of thousands of atoms – adalimumab, a monoclonal antibody used
43 for autoimmune disorders, has a molecular formula of C₆₄₂₈H₉₉₁₂N₁₆₉₄O₁₉₈₇S₄₆ (20,067 total atoms)
44 and a molecular weight of 144,190 Da.

45
46 Biologic drug efficacy is very sensitive to the secondary, tertiary, and even quaternary structure,
47 which describes how the molecule is folded and packed into shape.⁷ For example, many biosimilars
48 are antibody-based drugs, which require very specific folding patterns to generate the receptor
49 binding affinity needed to provide the drugs action in the body. The “active” portion of the
50 biosimilar may be a tiny fraction of the overall molecule while they also may contain several large
51 components that do not contribute meaningfully to the efficacy of the medication. As such,

1 biosimilars may have different chemical structures than their reference product, but if the
2 difference only exists in non-active portions of the structure and does not impact other elements
3 such as folding or polarity, then in theory they will retain similar efficacy.
4

5 To produce such complex moieties, biologic drugs are manufactured using unique strategies such
6 as bioreactors. Rather than pursuing traditional chemical synthesis, manufacturers leverage living
7 cells such as yeast or E. coli that are genetically modified to produce the desired product. Due to
8 the relative lack of control over bioreactor manufacturing, there can be high levels of both inter-
9 and intra-batch variability resulting in changes in protein sequence, higher order structure,
10 aggregation, charge heterogeneity, oxidation, and any byproducts from the bioreactor organism
11 that may impact drug function and immunogenicity.⁸ Additionally, since the organisms responsible
12 for producing the biologic drug are their own living system, they evolve and mutate over time,
13 meaning that the output will slowly, irreversibly drift over time.⁹ As such, there is significant
14 effort, from industry and regulators, dedicated to monitoring and probing biologic drug
15 manufacturing to ensure drug safety and efficacy are preserved in these manufacturing conditions.⁸
16 Differences in manufacturing of biologics and small molecule drugs result in another key
17 distinction – biosimilars are designed to have *similar* function and efficacy, but it is an impossible
18 task to ever perfectly reproduce composition and structure.
19

20 Considering their unique composition, mechanism of action, and manufacturing, biosimilars and
21 their approvals are regulated via their own distinct pathway by the FDA. Established by the
22 Biologics Price Competition and Innovation Act of 2009 (BPCIA, passed within the broader
23 Affordable Care Act), biosimilars are approved via an abbreviated 351(k) pathway compared to the
24 505(j) pathway for other small molecule generic drugs. Per the Hatch-Waxman Act, generic small
25 molecule drug manufacturers are only required to establish bioequivalence for FDA approval.¹⁰
26 Compared to small molecule generic drugs, biosimilar manufacturers are required to prove that
27 their product utilizes the same mechanism of action, analytical studies proving similarity of the
28 biologically active components, animal studies assessing toxicity, and clinical studies assessing
29 efficacy, immunogenicity, pharmacokinetics, and pharmacodynamics.¹¹ As a result, the cost
30 associated with developing, testing, and seeking approval for a biosimilar is significantly higher
31 than that of a generic drug – with some estimates as high as nine years and \$300 million per
32 biosimilar.^{12,13}
33

34 *Interchangeability*

35

36 There is a continuing tension in how to best describe biosimilars. On the one hand, biosimilar
37 naming and terminology needs to convey that they have been found to perform the same as the
38 reference product. Yet on the other hand, it needs to convey that they are chemically *similar* – not
39 identical. Due to the relative infancy of the field, the clinical implications have yet to be fully
40 understood, especially when there can be significant molecule structural or compositional
41 differences between biologic products that otherwise perform similarly.¹⁴⁻¹⁸
42

43 One of the primary sources of tension around communicating biosimilar drugs similarity and
44 differences is the utilization of the term “interchangeable.” As alluded to by the original Resolution
45 245-A-23, there are additional distinctions and implications between biosimilars and small
46 molecule generic drugs when it comes to interchangeability and pharmacy-level substitutions. Per
47 the BPCIA, “interchangeable” is an additional designation that can be given to biosimilars that
48 allows for pharmacists to perform a substitution of two biologic drugs, if allowed by their state
49 pharmacy laws, similar to generic small molecule drugs for their brand name product. Per the
50 Public Health Service Act, “the [term interchangeable in] reference to a biological product [...]

1 means that the biological product may be substituted for the reference product without the
2 intervention of the health care professional who prescribed the reference product.”¹⁹

3 Beyond the baseline evidence that manufacturers provide for biosimilar approval, to be deemed
4 “interchangeable” manufacturers must perform a switching study or interchangeable trial -- a two-
5 arm clinical trial in which one arm receives the reference product continuously, and the other
6 switches from the reference product to the biosimilar and back again. If there are no substantive
7 differences in efficacy or immunogenicity upon switching back and forth between biosimilar and
8 the reference product, the biosimilar may be deemed “interchangeable.” It should be noted that to
9 receive the initial FDA approval as a biosimilar, the drug must already have proven to have similar
10 efficacy and immunogenicity to the reference product. Instead, interchangeable trials are meant to
11 assess if there are any changes in efficacy and immunogenicity caused by the act of switching itself
12 after a patient has already initiated treatment.

13
14 The “interchangeable” designation is therefore used primarily by pharmacists for performing
15 medication substitutions. These medication substitutions are often required due to formulary
16 restrictions by pharmacy benefits managers, cost-savings to the patient or available stock, among
17 others. State laws vary greatly for how pharmacists may substitute biosimilars and other generic
18 small molecule drugs.²⁰ For example, in Illinois, a pharmacist may substitute a biologic product
19 with an approved interchangeable biosimilar after alerting the prescriber and the patient. In North
20 Carolina, however, pharmacists may only substitute interchangeable biologics if it will result in
21 cost savings for the patient, but they are not required to communicate this to the prescriber.

22
23 The international approach to biosimilar substitutions is mixed, which may be expected for a
24 relatively new class of highly complex medicines.²¹ The European Union’s regulatory arm, the
25 European Medicines Agency (EMA), does not have an additional category or testing requirements
26 for substitutions and deems all biosimilars approved by the EMA to be interchangeable. However,
27 individual member countries may have their own regulations.²²

28
29 Beyond its role in state-level pharmacy laws, the interchangeable designation is often one of
30 frustration for physicians, patients, and pharmacists. Due to their similarity to another drug,
31 patients may expect that a biosimilar can be substituted at the pharmacy like other generic small
32 molecule drugs, barring formulary restrictions. However, the interchangeability requirements leave
33 patients confused, bring added work for physicians and pharmacists to communicate access
34 challenges and mediate procurement of the appropriate agent to the patient. Further, educating
35 patients on the regulatory nuance between biosimilar and interchangeability can leave everyone
36 frustrated and confused with the process and potentially lead to treatment delays.

37
38 From a manufacturer’s perspective, the interchangeable designation is a highly desirable one. The
39 price of many biologic drugs is substantial, and being made available for pharmacy-level
40 substitutions may be a significant competitive advantage in a growing marketplace. In one instance,
41 the interchangeable designation of Semglee (insulin glargine-yfgn) resulted in the removal of the
42 reference product, Lantus (insulin glargine), entirely from major pharmacy benefit managers’ drug
43 formularies.²³ To further incentivize biosimilar developers to pursue interchangeable status, the
44 FDA allows for the first interchangeable biosimilar of a drug to obtain market exclusivity status for
45 a year.²⁴ However, given the high cost of bringing a biosimilar to market, performing an additional
46 clinical trial to evaluate switching may be an additional barrier to entry for smaller biosimilar
47 sponsors. Additionally, biologic drugs which have a biosimilar competitor available will be exempt
48 from Medicare drug price negotiations with the newly founded Drug Price Negotiation Program.²⁵

1 From a regulator’s perspective, the interchangeable designation likely seems to be a cautious step
2 towards regulating a new class of drugs where immunogenicity concerns are high. However, it is
3 unclear if those concerns have been realized. Additionally, much of the interchangeable framework
4 is directly outlined in the BPCIA, meaning it would require an act of Congress to significantly
5 change it.

6 7 REGULATORY MOVEMENT

8
9 According to the FDA’s Purple Book Database at the time of writing, there have been 45 biosimilar
10 products approved in the United States, and seven have received the interchangeable designation.²⁶
11 Clinical trial data for failed studies is generally not published, but there have been no indications
12 that any biosimilar which has pursued the interchangeable study has failed to achieve the
13 interchangeable designation.

14
15 In late 2023, scientists from the FDA’s Center for Drug Evaluation and Research published a meta-
16 analysis evaluating the outcomes of 44 treatment switches across 21 different biosimilars, with a
17 total of 5252 patients. In their review, they found that “no differences in terms of major safety
18 parameters such as deaths, [non-fatal serious adverse events], and discontinuations were observed
19 when patients are switched (to or from a biosimilar and its reference biologic) or not switched.”²⁷
20 This supports the findings of European regulators, which stated “[the] EMA has approved 86
21 biosimilar medicines since 2006. These medicines have been thoroughly reviewed and monitored
22 over the past 15 years and the experience from clinical practice has shown that in terms of efficacy,
23 safety and immunogenicity they are comparable to their reference products and are therefore
24 interchangeable.”²⁸

25
26 The above-mentioned FDA study appears to be part of a larger movement within the federal
27 government more broadly to re-evaluate the role of interchangeable status. In September 2023, the
28 FDA published a draft guidance to change the labeling for biosimilars.²⁹ Prior to this guidance,
29 biologic medicine labeling had two distinct sections: a “biosimilarity statement” and an
30 “interchangeability statement,” where if not deemed interchangeable, the statement would be
31 blank. Under the new guidance, the two are combined into a single statement to allow for those
32 who are legally required to understand interchangeability status to be easily able to find it on
33 product labeling, while prescribers or patients do not feel that their medication is of lower quality
34 when seeing a blank interchangeability statement.

35
36 These movements by the FDA away from the interchangeable designation are matched by other
37 federal entities. In a March 2022 report from the Office of the Inspector General (OIG), they found
38 that Medicare was over-spending on biologic medicines by not fully incorporating biosimilars into
39 their offerings, and instead focusing too heavily on reference products.³⁰ OIG estimated that
40 Medicare Part D spending on biologics could be decreased by 18 percent (\$84 million) annually,
41 and out-of-pocket spending on these products for Medicare beneficiaries could decrease by 12
42 percent (\$1.8 million) annually, if biosimilars were more broadly used.

43
44 Under current regulations, biosimilars may only be substituted with those deemed interchangeable,
45 and only after explicit approval by the Centers for Medicare & Medicaid Service (CMS). In
46 November 2023, CMS proposed rule changes to Medicare Advantage and Medicare Part D that
47 would allow for plans to immediately substitute all biosimilars, including those not deemed
48 interchangeable, for the reference product.³¹ On January 4th, 2024, the AMA submitted comment to
49 CMS on this proposed change, and cited concern that CMS movement was premature barring
50 regulatory changes from the FDA, and that patients currently receiving the reference product
51 should be exempt from substitutions without approval from their physician.

1 In March 2024, the Biden Administration released its draft budget for fiscal year 2025, which
2 included a policy proposal to allow for all biosimilars, regardless of interchangeability status, be
3 eligible for pharmacy level substitutions.³² At the time of this report’s writing (March 2024), it is
4 unclear if this policy will be included in the final, approved budget for fiscal year 2025, but it is
5 generally consistent with the direction federal regulations on biosimilar interchangeability has
6 taken in recent years.

7 8 CURRENT AMA POLICY

9
10 The AMA currently has several policies regarding biosimilars, particularly around reimbursement
11 and cost coverage. Of particular relevance to this report are two policies (full text of policies found
12 at the end of this report): (1) H-125.976 “Biosimilar Interchangeability Pathway,” states amongst
13 other clauses, that “[the AMA] strongly support the pathway for demonstrating biosimilar
14 interchangeability”; and (2) D-125.989 “Substitution of Biosimilar Medicines and Related Medical
15 Products,” which urges State Pharmacy Practice Acts to limit the authority of pharmacists to
16 substitute biosimilars only when they have been deemed interchangeable by the FDA.

17 18 CONCLUSION

19
20 At the crux of this issue is balancing patient access to medications against the unknown risks of a
21 newer class of highly complex medicines. Given the current state of the published evidence
22 between the European Union and FDA reviews, it appears that the previous concerns over toxicity
23 and immune response of switching biosimilars have not been realized. However, it is important to
24 recognize that the evidence on interchangeability is still limited and that the field of biosimilars is
25 in its infancy compared to our knowledge of generic small molecule drugs. Additionally, the term
26 interchangeable, however flawed, is utilized by several entities beyond the FDA, including for
27 Medicare reimbursement and state pharmacy laws. Therefore, the Council recommends that an
28 approach be taken to retain the FDA’s ability to assess and monitor potential risks of switching
29 without placing an outsized importance and advantage in the marketplace on the completion of
30 additional switching trials that have yet to yield value for patients and physicians.

31 32 RECOMMENDATIONS

33
34 The Council on Science and Public Health recommends that the following be adopted and the
35 remainder of the report be filed:

- 36
37 1. That Policy H-125.976, “Biosimilar Interchangeability Pathway” be rescinded. (Rescind
38 HOD Policy)
39 2. That our AMA encourage the FDA to continually collect data and critically evaluate
40 biosimilar utilization including the appropriateness of the term “interchangeable” in
41 regulatory activities. (Directive to Take Action)
42 3. That Policy D-125.989 “Substitution of Biosimilar Medicines and Related Medical
43 Products” be amended by addition and deletion to read as follows:

Our AMA urges that State Pharmacy Practice Acts and substitution practices for biosimilars in the outpatient arena: (1) preserve physician autonomy to designate which biologic or biosimilar product is dispensed to their patients; (2) allow substitution when physicians expressly authorize substitution of an interchangeable a biologic or biosimilar product; (3) limit the authority of pharmacists to automatically substitute only those biosimilar products that are deemed interchangeable by the FDA. in the absence of express physician authorization to the contrary, allow substitution of the biologic or biosimilar product when (a) the biologic product is highly similar to the reference product.

notwithstanding minor differences in clinically inactive components; and (b) there are no data indicating clinically meaningful differences between the biological product and the reference product in terms of the safety, purity, and potency of the product. (Modify Current HOD Policy)

4. That Policy D-125.987, “Biosimilar Product Naming and Labeling” be reaffirmed. (Reaffirm HOD Policy)

Fiscal note: less than \$1,000

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CITED AMA POLICIES

Biosimilar Interchangeability Pathway H-125.976

Our AMA will: (1) strongly support the pathway for demonstrating biosimilar interchangeability that was proposed in draft guidance by the FDA in 2017, including requiring manufacturers to use studies to determine whether alternating between a reference product and the proposed interchangeable biosimilar multiple times impacts the safety or efficacy of the drug; and (2) issue a request to the FDA that the agency finalize the biosimilars interchangeability pathway outlined in its draft guidance “Considerations in Demonstrating Interchangeability With a Reference Product” with all due haste, so as to allow development and designation of interchangeable biosimilars to proceed, allowing transition to an era of less expensive biologics that provide safe, effective, and accessible treatment options for patients.

Res. 523, A-18

Substitution of Biosimilar Medicines and Related Medical Products D-125.989

Our AMA urges that State Pharmacy Practice Acts and substitution practices for biosimilars in the outpatient arena: (1) preserve physician autonomy to designate which biologic or biosimilar product is dispensed to their patients; (2) allow substitution when physicians expressly authorize substitution of an interchangeable product; (3) limit the authority of pharmacists to automatically substitute only those biosimilar products that are deemed interchangeable by the FDA.

Res. 918, I-08. Modified: CSAPH Rep. 1, I-11. Modified: CSAPH Rep. 4, A-14.

Biosimilar Product Naming and Labeling D-125.987

Our AMA urges the FDA to finalize Guidance on the naming and labeling conventions to be used for biosimilar products, including those that are deemed interchangeable. Any change in current nomenclature rules or standards should be informed by a better and more complete understanding of how such changes, including requiring a unique identifier for biologic USANs would impact prescriber attitudes and patient access, and affect post marketing surveillance. Actions that solely enhance product identification during surveillance but act as barriers to clinical uptake are counterproductive. However, because of unique product attributes, a relatively simple way to identify and track which biosimilar products have been dispensed to individual patients must be established. If unique identifiers for biosimilar USANs are required to support pharmacovigilance, they should be simple and the resulting names should reinforce similarities by using the same root name following standards for nonproprietary names established by the USAN Council.

CSAPH Rep. 4, A-14

APPENDIX 1

Definitions of key terms:

Biologic drug (or large molecule drugs): a classification of drugs which are produced by living organisms (such as human or animal cells, yeast, or bacteria), rather than by chemical synthesis. As such, this class of drug tends to replicate or mimic common biologic entities. For example, antibody- or protein-based drugs are common examples of biologic drugs.

Small molecule drug: A classification of drugs based on the number of atoms (typically <100) in their structure. Small molecule drugs are generally prepared using chemical synthesis techniques. Small molecule drugs are estimated to represent over 90 percent of all pharmaceuticals used in the clinic today. Typically, small molecule drugs function by binding to a biological entity (protein, receptor, etc.) and altering its function.

Generic drug: A drug produced by a second manufacturer after the patent or other market protections have expired, allowing for manufacturers to be able to produce their own products with the same chemical substance as a branded drug. The term generic drug only applies to small molecule drugs, with few exceptions.

Biosimilar: A biologic drug that has a very similar structure and function to a branded biologic drug after its patent or market protections have expired. Unlike generic drugs, biosimilars are not required to be the same chemical compound, but they are required to have the same chemical structure to act on the body and efficacy.

Interchangeable: An additional designation provided for biosimilar drugs by the FDA. This designation is not required for market approval and indicates that a biosimilar has successfully demonstrated no changes in efficacy or immunogenicity when the biosimilar is substituted for the reference product after a patient has already initiated treatment with the reference product. This designation has implications for reimbursement, and state regulations around pharmacist practice.

APPENDIX 2

Table 1: Comparison of follow-on products for small molecule vs. biologic medicines.

Type of Medicine	<u>Small Molecule</u>	<u>Biologic</u>
<i>Name of Follow-on Product</i>	Generic	Biosimilar
<i>Drug Molecule Complexity</i>	Low	High
<i>Size</i>	Small (10s of Dalton)	Very Large (1000s of Dalton)
<i>Manufacturing Process</i>	Chemical synthesis	Bioreactor
<i>Characterization</i>	Simple	Complex
<i>Batch-to-Batch Variability</i>	Low	High, with potential for permanent formulation drift over time
<i>Regulatory Pathway</i>	Abbreviated New Drug Application	Abbreviated Biologics Licensing Agreement
<i>Can Pharmacist Make Substitution?</i>	Yes, if state pharmacy practice laws allow	Yes, if manufacturer successfully completes additional clinical trial where patients switch back and forth between reference and follow-on product AND state pharmacy practice laws allow
<i>Nonproprietary Name</i>	Same as reference product	Same as reference product with additional 4 letter suffix

REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 7-A-24

Subject: Androgen Deprivation in Incarceration

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

Referred to: Reference Committee E

NOTE FROM THE COUNCIL: This report discusses sexual crimes, including against minors. The policy question posed in this report centers on the medical treatment and rehabilitation of those who have been convicted of sexual crimes, often against minors. Please use caution when reading, discussing, disseminating, and debating the contents of this report as they may be re-traumatizing or triggering.

1 INTRODUCTION

2

3 Resolution 501-A-23, “AMA Study of Chemical Castration in Incarceration” was adopted and
4 states that “our AMA study the use of chemical castration in the treatment of incarcerated
5 individuals with paraphilic disorders and for other individuals who commit sexual offenses,
6 including ethical concerns over coercion in its use as an alternative to incarceration and in
7 probation and parole proceedings.”

8

9 This report serves as the Council on Science and Public Health’s response to this charge. For the
10 purposes of this report, the term “androgen deprivation” (AD) will be substituted for “chemical
11 castration” to be more consistent with scientific literature, and to avoid the potential confusion of
12 reversible AD with irreversible surgical castration, typically performed by surgical removal of the
13 testes (orchiectomy).

14

15 METHODS

16

17 English language articles were selected from searches of PubMed and Google Scholar using the
18 search terms “chemical castration”, “androgen deprivation”, “chemical castration AND
19 incarceration”, and “androgen deprivation AND incarceration”. Additional articles were identified
20 by manual review of the reference lists of pertinent publications. Web sites managed by
21 government agencies and applicable organizations were also reviewed for relevant information.

22

23 BACKGROUND

24

25 Sexual crimes can cause significant trauma in their victims. Survivors can be subject to a lifetime
26 of psychological trauma including self-blame, post-traumatic stress disorder, suicidal ideation, and
27 structural changes in the brain.¹⁻⁴ This may be further challenging for those who experience this
28 abuse at a younger age. However, incident rates of child sexual abuse may be difficult to properly
29 assess due to the nature of the victims – e.g., victims may not understand they have been the
30 victims of a crime, or they may rely on their assailant for their basic needs. One study estimates
31 that up to 27 percent of girls and eight percent of boys experience childhood sexual assault in the

1 United States.⁵ Per the U.S. Sentencing Commission, approximately 1,000 cases per year in Federal
2 courts involve sexual abuse, with 94 percent of offenders being men.⁶

3
4 The public perception of perpetrators of sexual crimes is extremely negative, resulting in the
5 feeling that actions against these offenders should be more punitive and less rehabilitative
6 compared to those who have committed non-sexual offenses.⁷ Due to the prevalence and the
7 severity of these crimes, along with the social outrage, public officials often seek non-traditional
8 approaches for dissuading future sexual abuse, such as sexual offender registries, which are outside
9 of the scope of this report.

10
11 One of the approaches, currently utilized in seven states (see Appendix 1), is the use of drugs to
12 lower testosterone levels, with the belief that lower testosterone will reduce the likelihood of an
13 individual committing a sexual crime. This report seeks to describe the current science in the
14 diagnosis and management of paraphilic disorders, examine the utilization of AD in the criminal
15 justice system, and discuss the ethical issues presented by legal mandates for AD in a carceral
16 setting.

17 18 PARAPHILIC DISORDERS, STIGMA, AND THE CRIMINAL JUSTICE SYSTEM

19
20 It is important to distinguish the difference between paraphilias and paraphilic disorders. Per the
21 Diagnostic and Statistical Manual of Mental Disorders (DSM), a paraphilia is “any intense and
22 persistent sexual interest other than sexual interest in genital stimulation or preparatory fondling
23 with phenotypically normal, physically mature, consenting human partners.”⁸ Examples of
24 paraphilic disorders included in the DSM are exhibitionistic disorder, voyeuristic disorder,
25 pedophilic disorder, and frotteuristic disorder. If the paraphilia is causing distress or impairment to
26 either the individual or another person, it may be classified as a paraphilic disorder. The presence
27 of a paraphilia itself does not necessarily warrant clinical intervention or a paraphilic disorder
28 diagnosis. Additionally, it is critical to distinguish between paraphilic thoughts and paraphilic
29 behaviors. This distinction is especially important when discussing criminal acts. Many individuals
30 with paraphilic disorders do not act upon their desires, but they are still distressing and the
31 individual would benefit from clinical support.⁹

32
33 Individuals with paraphilic disorders are subject to intense social stigma, which often results in
34 feelings of guilt, shame, and self-loathing.¹⁰ Clinically, this presents multiple issues, such as
35 individuals being less likely to seek care, and making it more difficult to recruit patients for clinical
36 trials of new treatments. This is particularly true in instances where individuals could be required to
37 disclose that they are experiencing urges to perform criminal acts, even if they do not act upon
38 them. As such, blanket approaches, particularly in the form of legal mandates, should be
39 approached with skepticism as to whether they are truly informed by research and best practices, or
40 a manifestation of the social stigma and bias towards punitive measures for those convicted of
41 sexual offenses. Many of those with paraphilic disorders are themselves survivors of abuse, often
42 experienced in childhood.¹¹

43
44 Treatment for paraphilic disorders is difficult and nuanced. Paraphilic disorders are highly
45 heterogeneous in their manifestation and presentation, ranging from urges to actions, which is
46 further complicated by the social stigma preventing many from seeking care. AD seeks to reduce
47 testosterone, and thus arousal. While this may be effective for some, many convicted of sexual
48 crimes report that they were not seeking sexual gratification, but rather acted out of grievance,
49 impulsivity, or a desire to exert control.¹² This highlights the intersection of many paraphilic
50 disorders with other psychological conditions, emphasizing the importance of consistent,

1 adjunctive psychotherapy, and why many pharmacotherapy approaches for paraphilic disorders go
2 beyond just AD, often including antidepressants, anxiolytics, and mood stabilizers.¹³⁻¹⁶

3 4 ANDROGEN DEPRIVATION IN A CLINICAL SETTING

5
6 AD therapy is a commonly accepted medical treatment approach for managing prostate cancers,
7 where hormones such as testosterone are required for cancer cell growth and proliferation.¹⁷
8 Medications used for AD regimens vary and include leuprorelin, goserelin, and triptorelin, but
9 generally the mechanism of AD action is either as an agonist or antagonist against luteinizing
10 hormone-releasing hormone (LHRH), resulting in a reduction of testosterone production. Patients
11 receiving AD for prostate cancer report loss of libido (up to 91 percent) and erectile dysfunction
12 (up to 95 percent).¹⁸ The high prevalence of sexual dysfunction, as well as the decrease in systemic
13 testosterone levels (and thus presumed decrease in behaviors associated with testosterone, such as
14 aggression) have led to the theoretical utility of AD for managing some types of paraphilic
15 disorders.

16
17 As AD influences hormones, the level of side effects particularly in long-term use can be serious.
18 In a long-term study of men with paraphilic disorders being administered triptorelin, 11 of 18 men
19 saw decreases in bone density, with other reported side effects including persistent hot flashes,
20 diffuse pain, and erectile dysfunction with age-appropriate sexual partners.¹⁹ Depot
21 medroxyprogesterone acetate (DMPA), which is the required medication for AD in the carceral
22 context in California (described below), is contraindicated for people with adrenal disease, severe
23 hypertension, risk of thromboembolic disease, diabetes mellitus, severe depressive disorder,
24 pituitary disease, and meningioma. These side effects often result in high rates of discontinuation,
25 which in the context of most state laws described later, would require the individual to return to
26 prison.²⁰ Due to the side effect profile, the duration of treatment is a critical component. In the
27 oncology setting, the duration of treatment is often on the scale of months, and there is some
28 interest in an intermittent approach (where patients cycle on and off treatment) to better manage
29 side effects.²¹ Patients with paraphilic disorders may receive AD for years, thus subjecting them to
30 more serious side effects.²²

31
32 The evidence base for AD as a treatment for paraphilic disorders primarily comprises of case
33 reports, small cohort, or uncontrolled studies. With those caveats, the current published works
34 generally support that AD may be effective for treating some people with paraphilic disorders. In
35 one study, 29 men previously convicted of sexual crimes and presenting with paraphilic behaviors
36 (child molestation, exhibitionism, or frottage) were treated with DMPA for six months.²³ In that
37 period, one reported committing a sexual crime, while most described a near complete suppression
38 of criminal sexual thoughts and activities. Another study of 46 male patients with paraphilic
39 disorders undergoing group psychotherapy found that patients receiving DMPA in conjunction
40 with psychotherapy had a lower relapse rate (15 percent) compared to those using psychotherapy
41 alone (68 percent).²⁴ These findings are generally observed across the literature, with a meta-
42 analysis (N = 22,181 persons across 69 total studies) finding that hormonal medication had an odds
43 ratio of 3.08 for remission (thoughts, actions, or both) compared to an odds ratio of 1.45 for
44 cognitive-behavioral therapy alone, with the caveat that most hormonal medication included in
45 their analysis was administered in conjunction with cognitive-behavioral therapy.²⁵

46
47 Finally, studies nearly universally focus on the impact of AD on men. While sexual crimes are
48 disproportionately committed by men (97 percent of arrests for rape and 93 percent of arrests for
49 other sexual crimes in 2019 were men), there is a noted lack of research available for treatment of
50 women and people of other gender identities with paraphilic disorders, particularly those which
51 may be utilizing hormone therapy for gender affirming care.²⁶

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ANDROGEN DEPRIVATION THERAPY IN THE CARCERAL SETTING

As of this writing, there are seven states (California, Florida, Iowa, Louisiana, Montana, Wisconsin, and Alabama) which use AD in some component of their judicial response to sexual crimes. A summary of state approaches is provided in Appendix 1 of this report. State approaches to AD generally vary over the level of discretion over who receives it, the duration, and whether it is tied to parole and/or probation.

In California, if an individual is convicted of a crime that is sexual in nature against a victim under the age of 13, a long-acting injection of DMPA may be a condition of their parole. If the individual has two convictions for sexual crimes against a minor, this injection is mandatory as a condition to receive parole.²⁷

In Florida, all individuals convicted of sexual assault (regardless of age of victim) may be required, at the discretion of the presiding judge, to receive AD upon completion of their prison sentence after consulting a medical professional, not necessarily a physician.²⁸ The judge can decide the duration of AD, which can be lifelong. If an individual does not appear for their court-mandated AD administration, they are charged with an additional felony. Similar to California, AD in Florida becomes mandatory upon a second conviction.

Alabama, which adopted its AD statute in 2019, allows judges to decide if someone convicted of sexual crimes against a victim under 12 years old will receive AD after their first offense. Additionally, those convicted in Alabama are required to pay for their AD for an indeterminate period of time, but inability to pay may not be used as the basis to deny parole. It is unclear at this time if court-mandated AD would be reimbursed by insurance.

Interestingly, there does not appear to be a clear trend in the recent actions of states and AD laws. For example, Alabama enacted its statute in 2019, while a legislator in New Mexico introduced an AD bill in 2021 but it failed to pass. Meanwhile, Oregon (2001) and Georgia (2006) both had AD statutes that have since been repealed. In Oregon, the law was a time-limited pilot program that was not renewed upon its conclusion.²⁹ In Georgia, references to AD were removed from laws as an unspecified “policy decision,” with no other public justification provided.³⁰

When trying to measure if AD laws are effective at reducing recidivism, it is critical to appreciate the difficulty in recruiting, retaining, and measuring behavioral outcomes in populations of those convicted of sexual crimes. This is a highly stigmatized population, and studies often require self-reporting of thoughts and actions and may involve confessing to a crime or thoughts that they feel deep shame towards. Efforts to measure recidivism as an endpoint are incredibly difficult to assess accurately due to the previously described factors which cause sexual violence to be underreported. This is especially true if AD is administered as a mandatory condition of parole. Individuals receiving parole are already a self-selecting population – they have indicated that they do not want to be incarcerated any more, meaning that incarceration is a deterrent for them. As such, individuals who receive AD as a condition of parole may already be a population less likely to re-offend, and the effect of AD on recidivism rates versus the fear of being incarcerated may be impossible to disentangle.

1 ETHICAL AND CONSTITUTIONAL CONCERNS

2
3 AD laws have been constitutionally challenged in state courts. For example, in 1984, a Michigan
4 man convicted of rape was sentenced to one year in prison and five years of probation only if he
5 received DMPA for AD.³¹ The Michigan Court of Appeals found in *People v. Gauntlett*, this
6 approach to be unconstitutional, with the rationale that DMPA was not FDA-approved for AD, and
7 that the individual could not provide informed consent if this was court-mandated administration.³²

8
9 While many AD laws in other states have not been challenged in courts, the outcome in Michigan
10 highlights several of the criticisms against AD laws. Beyond concerns of drug efficacy, safety, and
11 consent, there are additional concerns around the constitutionality of AD laws. For example, some
12 have argued that AD violates the Eighth Amendment's protection against cruel and unusual
13 punishment, or even that government intervention and mandating behavior-altering drugs may
14 violate an individual's First Amendment rights to have freedom of thought or mental autonomy.³³

15
16 Even in instances where an individual is provided a choice to receive AD, it is unlikely that this
17 would truly be free from coercion. The social stigma of those with paraphilic disorders can be
18 magnified in the carceral setting, and often results in those convicted of sexual crimes being
19 targeted for violence. One study, for example, found that individuals convicted of sexual crimes
20 made up 15 percent of an inmate population, but were the victims for over 30 percent of homicides
21 in prison.³⁴

22
23 Finally, while AD laws are intended to reduce the likelihood of committing additional sexual
24 crimes, they do impact fertility and selective enforcement harkens back to America's dark history
25 of eugenics. In the 1920s, dozens of states enacted eugenic sterilization laws, resulting in the
26 forceful sterilization of populations deemed undesirable – often inmates, and disproportionately
27 used against Black men and women.³⁵ Particularly in instances where the use of AD is at the
28 discretion of the court, legal scholars worry that racist stereotypes of hyper-sexual Black men will
29 result in disproportionately higher rates of AD administered to marginalized and minoritized
30 groups, which could serve as a modern eugenics law.³⁶

31
32 A review of the available literature was unable to identify analysis of the rate at which AD is used
33 in the carceral setting, nor the demographics of those receiving it.

34
35 CURRENT AMA POLICY

36
37 The AMA, through both its policy and administration of the Code of Medical Ethics, has a strong
38 history of opposing the use of medicine as punishment. Of particular relevance is Opinion 9.7.2,
39 "Court-Initiated Medical Treatment in Criminal Cases" (full text available at end of report), which
40 notes such treatments "raise important questions as to the rights of prisoners, the powers of judges,
41 and the ethical obligations of physicians" and that "medical ethics do not require a physician to
42 carry out civic duties [i.e., court-initiated medical treatments like AD] that contradict fundamental
43 principles of medical ethics." The Code states that physicians who participate in court-initiated
44 medical treatments should only do so "if the procedure being mandated is therapeutically
45 efficacious" and is "not a form of punishment." Additionally, the Code explains that physicians
46 should "[t]reat patients based on sound medical diagnoses, not court defined behaviors" and that
47 they should "[d]ecline to provide treatment that is not scientifically validated."

48
49 As of this writing, it is likely that state laws imposing AD fail to meet the standards set forth by the
50 Code of Medical Ethics. States either utilize automatic mandates or rely solely on the discretion of
51 the courts for deciding who requires AD, removing physician discretion and clinical judgement, as

1 well as eliminating the ability for the patient to provide consent. Additionally, some statutes
2 specifically cite that AD must be performed using DMPA, which has not been FDA-approved for
3 AD nor is it known to be included in any clinical guidelines for AD in the context of prostate
4 cancer or paraphilic disorder treatment.¹⁸ Finally, instances where AD may be optional as a
5 condition for parole or probation likely violate patient voluntariness, in that a patient is forced to
6 choose between extended incarceration or receiving a medicine, thus producing a highly coercive
7 situation.

8
9 CONCLUSION

10
11 Sexual crimes can cause significant trauma in their victims and survivors may experience a lifetime
12 of psychological trauma including self-blame, post-traumatic stress disorder, suicidal ideation, and
13 structural changes in the brain. The public perception of perpetrators of sexual crimes is extremely
14 negative, resulting in the feeling that actions against these offenders should be more punitive and
15 less rehabilitative. While policymakers have sought non-traditional approaches to reduce the
16 prevalence of sexual crimes in their communities, current state laws which remove physicians and
17 instead mandate AD for convicted sex offenders are not supported by science and are contrary to
18 the Code of Medical Ethics. AD should be viewed as a single tool in the physician's toolbox for
19 treating some paraphilic disorders and should only be initiated using informed consent and a
20 physician's best clinical judgement for a given patient and their circumstances, regardless of
21 whether the examination occurs in a prison or a clinic.

22
23 RECOMMENDATIONS

24
25 The Council on Science and Public Health recommends that the following be adopted and the
26 remainder of the report be filed:

- 27
28 1. That Policy H-430.977, "AMA Study of Chemical Castration in Incarceration" be
29 rescinded. (Rescind HOD Policy)
30
31 2. That our AMA:
32
33 a. Opposes laws, regulations, and actions of the court which remove physician
34 autonomy and clinical judgement from treatment decisions regarding androgen
35 deprivation (also known as chemical castration) for those convicted of sexual
36 crimes.
37 b. Opposes linkages of criminal sentencing, parole, or probation to court-mandated
38 androgen deprivation.
39 c. Encourages data collection on the utilization, court mandates, duration of therapy,
40 and clinical outcomes of androgen deprivation in the carceral setting.
41 d. Supports continued research for effective treatments for paraphilic disorders,
42 including efforts to reduce stigma and recruit patients with paraphilic disorders
43 into clinical trials. (New HOD Policy)
44
45 3. That Policies D-430.997, "Support for Health Care Services to Incarcerated Persons," H-
46 430.978 "Improving Care to Lower the Rate of Recidivism," and H-345.981 "Access to
47 Mental Health Services" be reaffirmed. (Reaffirm HOD Policy)

Fiscal note: less than \$1,000

APPENDIX 1

Table 1: Summary of state laws regarding androgen deprivation therapy (as of January 2024)

State	Code	Mandatory?	Age for victims and applications	Duration	Notes
Alabama	Section 15-22-27.4: Parole of persons convicted of sex offense involving person under 13 years of age	Discretion of court as a condition of parole	Sex crime with a victim under the age of 13	Can continue until the department of corrections deem no longer necessary	
California	CA Penal Code Section 645	First conviction: At court's discretion Second or subsequent conviction: Required	Any sex crimes against someone 13 years or younger	Continued until the Department of Corrections deems treatment no longer necessary	Specifically requires the use of medroxyprogesterone acetate.
Florida	Florida Statute 794.0235	First conviction: At court's discretion Second or subsequent conviction: Required	Applies to sexual battery convictions (adult or minors)	Duration will be determined by court and can be up to the life of the offender.	Requires a court appointed medical expert determination that defendant is appropriate candidate for treatment.
Iowa	903B.10 Hormonal intervention therapy	First conviction: At court's discretion Second or subsequent conviction: Required unless court or board of parole determines the treatment would not be effective	For "serious sex offenses" with a minor under the age of 12 (sexual abuse of all degrees, assault, and sexual exploitation)	Treatment will continue until the agency in charge of supervision deems no longer necessary.	Offenders have to pay a "reasonable fee" to pay for the costs of treatment
Georgia	Formerly Ga. Code Ann. § 16-6-4 (2002) and Ga. Code Ann. § 42-9-44.2 (2002)	n/a	n/a	n/a	Repealed in 2006
Louisiana	RS 14:43:6	First conviction: At court's discretion Second or subsequent conviction: Required	All cases of first- or second-degree rape, OR sexual battery and molestation when the victim is under 13	Court will specify the duration of treatment, up to the life of the defendant.	Requires a court appointed medical expert determination that defendant is appropriate candidate for treatment

State	Code	Mandatory?	Age for victims and applications	Duration	Notes
Montana	45-5-212 Assault on minor	First conviction: At court's discretion Second or subsequent conviction: Required	Applies to all convictions (adult or minors) of: -Sexual assault -Rape -Incest	Can continue until the department of corrections deem no longer necessary	
Oregon	Formerly Ore. Rev. Stat. § 144.625 (2001), Ore. Rev. Stat. § 144.627 (2001), Ore. Rev. Stat. § 144.629 (2001), Ore. Rev. Stat. § 144.631 (2001)	n/a	n/a	n/a	Repealed in 2001
Wisconsin	Wisconsin Statutes, Section 302.11(1)(b)2 Wisconsin Legislative Council IM-2021-07: Requirement for chemical castration	Discretion of Department of Corrections of Parole Commission	Sex crimes with a victim below the age of 13	Unspecified	

CITED AMA POLICY

Opinion 9.7.2, “Court-Initiated Medical Treatment in Criminal Cases”

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

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

- (1) Participate only if the procedure being mandated is therapeutically efficacious and is therefore undoubtedly not a form of punishment or solely a mechanism of social control.
- (2) Treat patients based on sound medical diagnoses, not court-defined behaviors. While a court has the authority to identify criminal behavior, a court does not have the ability to make a medical diagnosis or to determine the type of treatment that will be administered. When the treatment involves in-patient therapy, surgical intervention, or pharmacological treatment, the physician’s diagnosis must be confirmed by an independent physician or a panel of physicians not responsible to the state. A second opinion is not necessary in cases of court-ordered counseling or referrals for psychiatric evaluations.
- (3) Decline to provide treatment that is not scientifically validated and consistent with nationally accepted guidelines for clinical practice.
- (4) Be able to conclude, in good conscience and to the best of his or her professional judgment, that to the extent possible the patient voluntarily gave his or her informed consent, recognizing that an element of coercion that is inevitably present. When treatment involves in-patient therapy, surgical intervention, or pharmacological treatment, an independent physician or a panel of physicians not responsible to the state should confirm that voluntary consent was given.

Support for Health Care Services to Incarcerated Persons D-430.997

Our AMA will:

- (1) 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;
- (2) encourage all correctional systems to support NCCHC accreditation;
- (3) encourage the NCCHC and its AMA representative to work with departments of corrections and public officials to find cost effective and efficient methods to increase correctional health services funding;
- (4) continue support for the programs and goals of the NCCHC through continued support for the travel expenses of the AMA representative to the NCCHC, with this decision to be reconsidered every two years in light of other AMA financial commitments, organizational memberships, and programmatic priorities;
- (5) work with an accrediting organization, such as National Commission on Correctional Health Care (NCCHC) in developing a strategy to accredit all correctional, detention and juvenile facilities and will advocate that all correctional, detention and juvenile facilities be accredited by the NCCHC no later than 2025 and will support funding for correctional facilities to assist in this effort; and
- (6) support an incarcerated person’s right to: (a) accessible, comprehensive, evidence-based contraception education; (b) access to reversible contraceptive methods; and (c) autonomy over the decision-making process without coercion.

Improving Care to Lower the Rate of Recidivism H-430.978

Our American Medical Association will advocate and encourage (1) federal, state, and local legislators and officials to increase access to community mental health facilities, community drug rehabilitation facilities, appropriate clinical care, and social support services (e.g., housing, transportation, employment, etc.) to meet the needs of indigent, homeless, and released previously incarcerated persons; and (2) federal, state, and local legislators and officials to advocate prompt reinstatement in governmental medical programs and insurance for those being released from incarceration facilities.

Access to Mental Health Services H-345.981

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

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

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Subject: Decreasing Regulatory Barriers to Appropriate Testosterone Prescribing

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

Referred to: Reference Committee E

1 INTRODUCTION

2
3 Our American Medical Association (AMA) House of Delegates referred the second Resolve of
4 Resolution 519-A-23, “Decreasing Regulatory Barriers to Appropriate Testosterone Prescribing.”
5 The referred resolve asked that our AMA study the outcomes of expanding access to testosterone
6 through decreasing state and health insurer regulatory requirements. In addition to the process
7 limitations, other barriers to care for testosterone prescribing include prescription drug monitoring
8 program (PDMP) state database reporting, telehealth, 30-day supply, and mail delivery limitations.
9

10 METHODS

11
12 English-language reports were selected from a PubMed and Google Scholar search through
13 January 2024, using the text terms “testosterone,” “prescribing,” “barriers,” and “regulations.”
14 Additional articles were identified by manual review of the references cited in these publications.
15 Further information was obtained from the Internet sites of medical specialty societies, federal and
16 state agencies, human rights organizations, legal organizations, among others to identify regulatory
17 and legal barriers to testosterone treatments, prescribing, and access when medically indicated.
18

19 BACKGROUND

20
21 Testosterone is a hormone that is naturally produced in the body of all individuals. Testosterone
22 replacement therapy (TRT) has been explored as a therapy for a variety of conditions, including
23 low serum testosterone levels, hypogonadism, erectile dysfunction, osteoporosis, diabetes mellitus,
24 and hypoactive sexual desire disorder.¹⁻⁷ Synthetic testosterone is classified as an anabolic-
25 androgenic steroid designed to mimic natural testosterone.
26

27 Testosterone is also a vital component of gender affirming hormone therapy (GAHT) for
28 transgender, non-binary, and/or gender diverse (TND) individuals, aiding in the development of
29 secondary sex characteristics aligning with their gender identity including physical changes such as
30 increased muscle mass and strength, fat redistribution, cessation of menstrual periods, heightened
31 sex drive, facial and body hair growth, deepening of voice, and clitoral enlargement, among
32 others.^{8,9} These effects may begin within 1-6 months, while some may take up to 2-5 years after
33 initiating therapy. The effects may significantly alleviate gender dysphoria, depression,
34 psychological symptoms, and suicidality while enhancing overall quality of life, interpersonal
35 functioning, psychological adjustment, sexual function, body satisfaction, and self-esteem among
36 TND individuals.^{8,10,11} GAHT is often maintained throughout life, and discontinuation of hormone
37 therapy can lead to bone loss in TND individuals, particularly those who have undergone gonad
38 removal, which highlights the importance for access to this therapy.¹²

1 Testosterone, when prescribed as part of medically monitored GAHT, is generally considered safe,
2 with severe side effects being exceptionally rare.¹³ Concerns regarding associations between
3 testosterone and severe adverse effects, including mood alterations and cardiovascular disease,
4 stem from administering multiple testosterone derivatives at doses ranging from 10 to 100 times
5 higher than the normal physiologic levels. Individuals using high doses of testosterone have
6 reported withdrawal symptoms, such as depression, fatigue, irritability, loss of appetite, decreased
7 libido, and insomnia.¹⁴ TRT, as compared to performance enhancing use, includes testosterone
8 prescriptions within the physiological dosage range which is considered safe. Studies consistently
9 demonstrate significant positive effects on various aspects of mental health and well-being among
10 patients on TRT.^{13,15} However, health care experts have called for further research into the long-
11 term risks associated with testosterone products, including its potential impact on cardiovascular
12 health and the occurrence of breast/chest and endometrial cancers.^{16, 13,17-19}

13 14 DISCUSSION

15 16 *Policy Affecting Appropriate Testosterone Prescribing in the United States*

17
18 Recently, there has been a significant increase in state laws banning gender affirming care (GAC)
19 including GAHT for TND people. Across the nation, state legislatures, governors, and
20 administrative agencies are increasingly implementing measures to limit access to gender-affirming
21 care, particularly targeting youth. GAC is supported by all major medical associations representing
22 over 1.3 million U.S. physicians, including the AMA.²⁰

23
24 Since 2021, 23 states have enacted laws that prohibit healthcare professionals from providing
25 gender-affirming medical interventions, including hormone therapy and surgeries, to minor
26 patients.²¹ These legislative measures effectively ban evidence-based care for TND youth by
27 imposing legal and professional penalties on health care professionals who provide GAC.²² Some
28 states have also taken steps to limit access to GAC for adults.²³ In addition to limiting access to
29 medically necessary care, providers of GAC have also been threatened with violence, jeopardizing
30 physician safety and practice.²⁴

31
32 On a national level, in 2021, U.S. Department of Health and Human Services (HHS), Office for
33 Civil Rights (OCR) expanded its interpretation and enforcement of Section 1557 of the Affordable
34 Care Act (ACA) and Title IX of the Civil Rights Act, to include protection against discrimination
35 based on sexual orientation and gender identity, ensuring access to GAC.²⁵ This was reiterated in
36 2022, when HHS issued a notice affirming its support for TND youths' access to gender-affirming
37 care.²⁶

38 39 *Regulatory Barriers to Appropriate Testosterone Prescribing*

40
41 The primary regulatory obstacle to appropriate testosterone prescribing, in addition to state-based
42 laws restricting care for TND patients, is its controlled substance scheduling status. Testosterone is
43 currently categorized as a Schedule III drug under the Controlled Substances Act (CSA). Such
44 classification indicates a potential for misuse, in addition to a potential to lead to physical
45 dependence or psychological dependence.²⁷ Uniquely, testosterone was added to the Controlled
46 Substances Act by the Anabolic Steroids Control Act of 1990, which classified all anabolic steroids
47 as schedule III-controlled substances, with the aim to stop chemical performance enhancement in
48 sports.²⁸ Congress effectively circumvented FDA's regulatory authority, by bypassing the typical
49 scientific and evidence review to inform scheduling.²⁹ The act faced opposition from the AMA, the
50 FDA, and the National Institute on Drug Abuse and despite this opposition was enacted by
51 Congress.²⁹⁻³¹

1 As a Schedule III controlled substance, testosterone is subject to more stringent regulations
2 compared to other prescription medications. Regulations on controlled substances include shorter
3 validity periods for prescriptions (physicians must rewrite prescriptions every 6 months),
4 limitations on refill quantities (limited to 30-day supplies), and potential exclusions from telehealth
5 and mail-order services of testosterone. Testosterone restrictions necessitate frequent
6 communication between individuals using testosterone and their prescriber to maintain a
7 continuous supply.²⁹ Amid the COVID-19 pandemic, temporary adjustments in regulations enabled
8 individuals to acquire 100-day medication supplies via mail services, however testosterone
9 remained exempt from these alterations due to its classification as a controlled substance.^{29,32}

10 11 *Prescription Drug Monitoring Programs*

12
13 PDMPs are state-level electronic databases intended for public health surveillance, prescription
14 monitoring, and to inform clinical decision-making. PDMPs track dispensed prescriptions based on
15 the schedule level designated in the state controlled substances act (CSA). As of 2023, eight states
16 monitor schedule II – IV via their PDMP, 45 states, territories, and districts monitor Schedules II
17 through V, 32 states track “drugs of concern” (i.e., drugs not scheduled under their state CSA), and
18 one state monitors all prescription medications.³³ Currently, testosterone is a monitored substance
19 in all state PDMPs. Patients have raised concerns regarding the surveillance of medications,
20 including fears of being outed by their health care professionals, pharmacists, law enforcement and
21 others with access to their states’ PDMP data.³⁴

22
23 Almost all PDMPs can be used by court officials, probation and parole officers, and law
24 enforcement agencies to prevent controlled substance diversion or monitor a patient’s prescription
25 use with a court order, search warrant, or subpoena.³⁵ Law enforcement permission to access
26 PDMPs varies by state. As of 2022, 25 states require an active investigation or “official duties,” 18
27 require a subpoena, 17 require a court order, and 11 require a search warrant to view PDMP
28 records.^{36,37} (See Table 1) Some states have multiple forms of law enforcement access requirements
29 that are accepted.⁵⁵ As GAC becomes criminalized in some states, access to this data by law
30 enforcement could be devastating for patients.

31
32 HIPAA’s Privacy Rule regulates the use and disclosure of protected health information (PHI) by
33 covered entities, but it does not specifically include PDMP data. In December 2023 members of
34 Congress urged HHS to revise the Health Insurance Portability and Accountability Act (HIPAA)
35 regulations to include PDMPs, after briefings with major pharmacies revealed that law enforcement
36 agencies were secretly obtaining thousands of prescription records without a warrant.³⁸ All eight
37 major pharmacy chains reported that “they do not require a warrant prior to sharing pharmacy
38 records with law enforcement agents, unless there is a state law that dictates otherwise.”³⁸ Gaps in
39 federal privacy coverage of both medical, prescription, and PDMP data raises concerns to deter
40 physician prescribing, pharmacist dispensing, and patients procuring medically indicated
41 testosterone.³⁹ Ongoing research is essential to investigate the unintended consequences associated
42 with granting law enforcement access to medical prescription histories, especially in the absence of
43 a court order.

44 45 *Insurer or Payer Barriers to Testosterone Prescribing and Access*

46
47 Many transgender individuals do not have health insurance. Those with health insurance often
48 encounter challenges with public and private insurers denying coverage for GAC, leaving patients
49 with large out-of-pocket cost.^{40–42} Findings from a 2022 nationally representative survey by the
50 Center for American Progress show that over 25 percent of transgender participants faced denials
51 for hormone therapy by health insurance providers.⁴³ According to the 2022 Employee Benefits

1 Survey, among the 30 percent of U.S employer-provided health plans providing GAC, only 25
2 percent cover GAC-related prescription drug therapy.⁴⁴ Moreover, only 26 percent include
3 physician visits for GAC and only 21 percent cover GAC-related lab tests, both of which are
4 typically necessary to be prescribed testosterone.⁴⁴

5
6 Even though a large number of insurance companies now provide coverage to TND individuals
7 because of federally mandated laws, many continue to deny coverage.⁴⁵ In 2021, 13 states reported
8 that coverage of GAHT is not addressed in their states' statute or policy, and 2 states exclude
9 coverage of GAHT.⁴⁶ The U.S. Transgender Survey reports that of adults utilizing GAHT, 21
10 percent (2,526 insured patients) of treatment claims have been denied.⁴⁷ Beyond these denials,
11 TND individuals report various insurance-related hurdles, such as difficulties in obtaining coverage
12 for GAC and other medical services, updating health insurance records, and issues related to
13 network adequacy.⁴³ For example, individuals with insurance often need to obtain prior
14 authorization before testosterone can be covered, delaying care up to 7 business days or more.⁴⁸
15 Among TND individuals, nonprescription hormone use is significantly higher among those whose
16 claims were denied or were uninsured.⁴⁷

17
18 Testosterone access is further complicated by insurance industry formulary drug tiers, in which
19 "non-preferred" testosterone products are restricted via prior authorization or higher cost-sharing
20 requirements.⁴⁶ In 2021, 34 out of 51 state Medicaid programs covered GAHT, while nine states
21 and two territories did not provide coverage.⁴⁹ Confirmation regarding GAHT coverage could not
22 be verified for eight states and three territories.⁴⁹

23
24 There have been some successful initiatives to improve GAC accessibility through the expansion of
25 state Medicaid essential health benefit plans and the explicit inclusion of GAC, including GAHT,
26 in state Medicaid coverage laws.⁵⁰ For instance, in 2023 Colorado became the first state to
27 explicitly integrate gender-affirming care to treat gender dysphoria, encompassing surgical
28 procedures, hormone therapy, and mental and behavioral health services, into its benchmark health
29 insurance plan for essential health benefits.⁵¹ While further studies are needed to assess the impact
30 of Colorado's expanded care, the coverage of GAC contributes to improved health outcomes while
31 reducing gender dysphoria, depression, anxiety, and suicidality among TND Coloradans.^{52,53}

32 33 AMA POLICY AND ADVOCACY

34
35 The AMA has robust policy regarding gender-affirming care, patient privacy, health equity,
36 medical necessity, protecting the provider-patient relationship, telehealth, and prior authorization.
37 Of particular relevance to this report is AMA Policy H-185.927, "Clarification of Evidence-Based
38 Gender-Affirming Care," which emphasizes the importance of evidence-based gender-affirming
39 care as determined through shared decision making between patients and physicians. This policy
40 instructs our AMA to "oppose laws and policies that criminalize, prohibit or otherwise impede the
41 provision of evidence-based, gender-affirming care" and to "advocate for federal, state, and local
42 laws and policies to protect access to evidence-based care for gender dysphoria and gender
43 incongruence." Additionally, our AMA advocates for equitable coverage of gender-affirming care
44 by health insurance providers, both public and private, through Policy H-185.950, "Removing
45 Financial Barriers to Care for Transgender Patients."

46
47 AMA policy H-315.983, "Patient Privacy and Confidentiality," affirms that HIPAA should be the
48 minimal standard for protecting client-patient privilege, and that law enforcement agencies
49 requesting private medical information should only be given access through a court order granted
50 through clear and convincing evidence, with the records subject to stringent security measures.

51

1 Further, Policy G-605.009 directs the AMA to convene experts and stakeholders to “identify issues
2 with physician payment and reimbursement for gender-affirming care and recommend solutions to
3 address these barriers to care.” The Task Force to Preserve the Patient-Physician Relationship
4 When Evidence-Based, Appropriate Care Is Banned or Restricted has invited interested Federation
5 partners to participate and is in the process of implementing this policy.
6

7 Protecting access to GAC has been a priority for the AMA for many years. Since the legislative
8 attempts to ban GAC first emerged, the AMA has been working closely with state medical
9 associations to oppose these inappropriate intrusions in the practice of medicine. The AMA has
10 submitted testimony and sent letters to legislators in several states and has assisted behind-the-
11 scenes in many more states. In 2021, the AMA also publicly urged governors across the country to
12 reject state legislation aimed at prohibiting medically necessary gender affirming care for minor
13 patients.⁵⁴ AMA advocacy has also supported state “shield laws” to protect physicians who provide
14 GAC and their patients from interstate enforcement of GAC bans and promote telehealth access to
15 GAC. The AMA has also been very active in litigation and has submitted numerous amicus briefs
16 urging courts to overturn laws that ban GAC.
17

18 Additionally, in 2019 the AMA published an issue brief with GLMA emphasizing the importance
19 of health insurance coverage for transgender patients and asserting the medical community's duty
20 to advocate for evidence-based care, reiterating that medical decisions should be made by patients,
21 their relatives and health care professionals, not politicians.⁵⁵ Lastly, in response to policy that was
22 adopted at the 2023 Annual Meeting Annual, D-270.983, “Decreasing Regulatory Barriers to
23 Appropriate Testosterone Prescribing,” the AMA asked the FDA to review the evidence on
24 testosterone, with the possibility of updating recommendations to send to the DEA regarding its
25 scheduling. In this letter the AMA conveyed concerns to the FDA Commissioner about the current
26 scheduling of testosterone-containing drug products, suggesting that the existing schedule may
27 unnecessarily restrict access to care for patients in critical need.⁵⁶
28

29 CONCLUSION

30

31 Addressing regulatory obstacles to appropriate testosterone prescribing requires a multifaceted
32 approach that encompasses both physician and patient perspectives. Initiatives such as rescheduling
33 testosterone to expand access through telehealth and reducing regulation on dispensing are crucial
34 steps toward ensuring equitable access to care. These measures not only enhance the availability of
35 testosterone therapy but also promote patient-centered care by facilitating access to qualified health
36 care professionals regardless of geographic location. Legislative and regulatory efforts must focus
37 on addressing barriers such as the lack of confidentiality, privacy, and security of medical health
38 data, which can undermine patient trust and deter individuals from seeking necessary care.
39

40 RECOMMENDATIONS

41

42 The Council on Science and Public Health recommends that the following be adopted, and the
43 remainder of the report be filed:
44

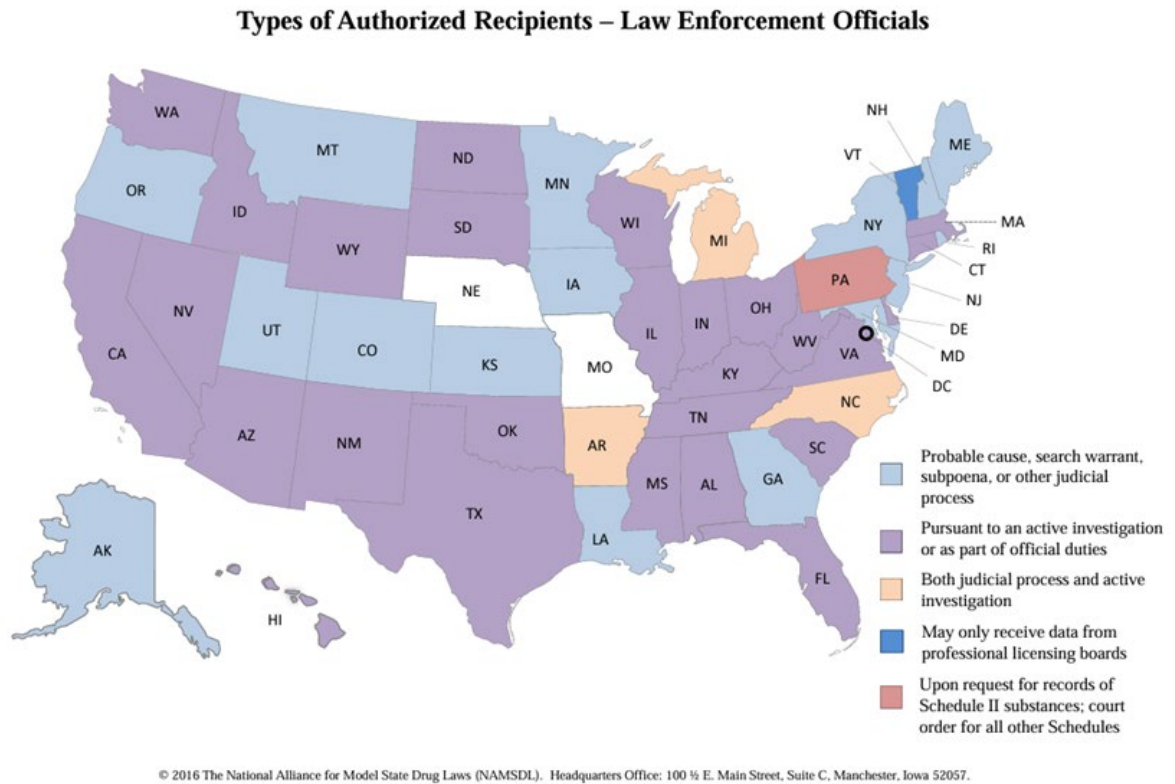
- 45 1. That policy D-270.983, “Decreasing Regulatory Barriers to Appropriate Testosterone
46 Prescribing,” be amended by addition to read as follows:
47
48 A. Our AMA will ask the FDA to review the available evidence and other data on
49 testosterone and submit updated recommendations, if warranted, to the DEA, for its
50 consideration of the scheduling of testosterone-containing drug products.
51

- 1 B. Our AMA supports policies to remove barriers that delay or impede patient access to
2 prescribed testosterone. (New HOD Policy)
3
4 C. Our AMA will continue to work alongside our partner organizations to promote
5 advocacy and physician education on testosterone prescribing. (New HOD Policy)
6
7 2. That Policies H-65.976, “Nondiscriminatory Policy for the Health Care Needs of LGBTQ
8 Populations,” H-140.824, “Healthcare Equity Through Informed Consent and a
9 Collaborative Healthcare Model for the Gender Diverse Population,” H-160.991, “Health
10 Care Needs of Lesbian, Gay, Bisexual, Transgender and Queer Populations,” H-185.927
11 “Clarification of Evidence-Based Gender-Affirming Care,” H-95.946, “Prescription Drug
12 Monitoring Program Confidentiality,” H-315.983, “Patient Privacy and Confidentiality,”
13 D-185.981, “Addressing Discriminatory Health Plan Exclusions or Problematic Benefit
14 Substitutions for Essential Health Benefits Under the Affordable Care Act,” and D-
15 480.964, “Established Patient Relationships and Telemedicine” be reaffirmed. (Reaffirm
16 HOD Policy)

Fiscal Note: less than \$1,000

TABLE 1. The National Alliance for Model State Drug Laws Map of The Types of Authorized Recipients of PDMP Information – Law Enforcement Officials

The National Alliance for Model State Drug Laws. *Compilation of Prescription Monitoring Program Maps*. The National Alliance for Model State Drug Laws; 2016. Accessed January 31, 2024. <https://namsdl.org/wp-content/uploads/Compilation-of-Prescription-Monitoring-Program-Maps.pdf>



Note: As of 2019, Nebraska requires a subpoena, court order or approval, and a written request.⁵⁷ As of 2021, Missouri requires a subpoena, court order or approval for law enforcement to access their state PDMP.⁵⁸

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REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 12-A-24

Subject: Universal Screening for Substance Use and Substance Use Disorders during Pregnancy

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

Referred to: Reference Committee E

1 INTRODUCTION

2

3 American Medical Association (AMA) Policy H-95.906, “De-Stigmatization and Management of
4 Substance Use Disorders” as adopted at the 2023 Annual Meeting asks that our AMA study the
5 feasibility, potential methodologies, and implications of early universal screening for substance use
6 and substance use disorders during pregnancy.

7

8 At the meeting, robust testimony was heard regarding screening with concerns being raised
9 regarding the complexity of screening when paired with mandatory reporting requirements. This
10 report investigates the implications, feasibility, and methodology of universal screening for
11 substance use and substance use disorders during pregnancy. This report serves as the Council on
12 Science and Public Health’s (CSAPH) findings and recommendations regarding universal
13 screening for substance use and substance use disorders during pregnancy.

14

15 METHODS

16

17 English-language reports were selected from a PubMed and Google Scholar search through
18 November 2023, using the text terms “screening”, “universal screening”, “pregnancy”, and
19 “substance use.” Additional articles were identified by manual review of the references cited in
20 these publications. Further information was obtained from the Internet sites of specialty physician
21 societies, federal and state agencies, U.S. Department of Health and Human Services (HHS), and
22 U.S. Preventive Services Task Force (USPSTF) to identify validated screening tools,
23 recommendations, clinical guidelines, and position statements.

24

25 BACKGROUND

26

27 Nationally, one in five people use illicit substances during pregnancy.¹ Polysubstance use, which is
28 defined as the use of two or more substances, is also common during pregnancy.² Data suggests
29 that 38.2 percent of pregnant women who drink alcohol also report using one or more substance,
30 the most common being tobacco and cannabis.² Overdose rates during pregnancy and the
31 postpartum period increased 81 percent (from 6.56 to 11.85 per 100,000) from 2017 to 2020.³ This
32 trend has been exacerbated by the COVID-19 pandemic, leading to a surge in overdose-related
33 deaths and intensifying concerns about pregnancy-associated substance use, primarily driven by
34 synthetic opioids and psychostimulants (e.g., fentanyl, methamphetamine, cocaine).³⁻⁵ In an
35 analysis of data from 2017-2019 by the Centers of Disease Control, mental health conditions,
36 including overdose and poisoning related to substance use disorder (SUD), were the leading causes
37 of pregnancy-related death.⁶

1 Despite pregnancy offering a critical window for engaging individuals in medical care, pregnant
2 individuals with SUD, particularly opioid use disorder (OUD), often avoid both prenatal and
3 preventive health care due to stigma, discrimination, inaccessibility of services, and prosecution or
4 loss of infant custody.^{7,8} Compounding these barriers, pregnant individuals with SUD face
5 substantial complications linked to poorer obstetric and neonatal health outcomes including the
6 pregnant persons' mortality, poor fetal growth, preterm birth, neonatal abstinence syndrome, and
7 other conditions.⁹ Even for those who are receiving treatment, returning to substance use in the
8 postpartum period is prominent and can often result in fatal overdose due to decreased tolerance. In
9 the postpartum period, overdose rates peak 7 to 12 months post-delivery for pregnant people who
10 use substances.^{10,11} During this critical period, treatment adherence is further complicated by the
11 physical need of the infant for maternal bonding.¹²

12
13 Persistent racial disparities in perinatal OUD treatment contribute to significant challenges. Studies
14 indicate that Black and Hispanic women are less likely to receive medications for opioid use
15 disorder (MOUD) compared to their White counterparts.^{13,14} Moreover, these challenges are
16 compounded by further racial disparities, particularly affecting individuals of color, notably
17 American Indian and Alaskan Native women, who encounter discrimination within both the health
18 care system and the family regulation system.^{15,16} Rural communities, despite experiencing higher
19 rates of substance exposure in utero, encounter additional barriers in accessing essential care.^{8,17}
20 These disparities are indicative of broader social and economic inequities, including heightened
21 obstacles to reproductive health care, underscoring the urgent need for targeted interventions and
22 systemic changes.

23 24 DISCUSSION

25
26 Identification of substance use at any point during a pregnancy can support improved patient
27 outcomes within the parent-infant dyad. AMA policy H-320.953, "Definitions of 'Screening' and
28 'Medical Necessity,'" defines screening as "health care services or products provided to an
29 individual without apparent signs or symptoms of an illness, injury or disease for the purpose of
30 identifying or excluding an undiagnosed illness, disease, or condition." Screening can be conducted
31 using brief, in-depth, written, verbal, or computerized screening instruments and does not include
32 biological specimens, such as urine or blood.¹⁸ Universal screening, involving the screening of
33 every pregnant individual, is designed to minimize clinician bias in individualized screening
34 decisions and promote more standardized care while also destigmatizing substance use disorders.

35
36 Clinical screening tools recommended for prenatal substance use include the Prenatal Substance
37 Abuse Screen for Alcohol and Drugs also known as the "4Ps" which stands for Parents, Partner,
38 Past, and Present.¹⁹ The 4Ps and the 4Ps Plus, which includes additional questions about depression
39 and domestic violence are the only validated behavioral health screening instruments designed
40 specifically for pregnant women.²⁰ The 4Ps Plus screener is one of the only validated tools for
41 substance use during pregnancy demonstrating overall reliability of 0.62, relatively high sensitivity
42 (87 percent), and specificity (76 percent).²¹ Additionally, the CRAFFT instrument is recommended
43 for screening substance use in adolescents and young adults, generally from ages 12 to 21.²² The
44 CRAFFT instrument has shown efficacy in detecting adolescent substance use, but it has not been
45 thoroughly evaluated for use during pregnancy. Lastly, the National Institute on Drug Abuse
46 (NIDA) Quick Screen is validated for screening for substance use in adults, but has not been
47 validated for screening for pregnant individuals.²³ Despite screening instruments demonstrating
48 strong performance on certain metrics, none exhibit consistently adequate performance across all
49 studied measures. For example, in one study the NIDA Quick Screen exhibited notable specificity
50 (0.99) across all substances but displayed very poor sensitivity (0.10–0.27). Often, screening
51 instruments exhibit significant variations based on race, prenatal clinic, and economic status.²³

1 Future research endeavors should aim to identify the most effective screening instrument for
2 substance use during pregnancy.²⁴

3
4 Current clinical guidelines address screening for substance use. The American Society of Addiction
5 Medicine (ASAM) and American College for Obstetricians and Gynecologists (ACOG)
6 recommend early universal screening for substance use during the first prenatal visit using a
7 validated screening to improve maternal and infant outcomes, advising early universal screening,
8 brief intervention, and referral for treatment (SBIRT) model for the treatment of pregnant patients
9 with OUD.²⁵ The SBIRT model has demonstrated effectiveness for reducing substance use.²⁶
10 Universal screening for opioid use is recommended instead of screening based factors such as
11 “poor adherence to prenatal care or prior adverse pregnancy outcomes” to minimize missed cases
12 of substance use as well as provider stereotyping and stigmatization of patients.²⁵ ASAM and
13 ACOG committee opinion stresses the importance of a coordinated multidisciplinary approach
14 without criminal sanctions for optimal support of the parent-infant dyad, discouraging health care
15 professionals from separating the parent-infant dyad based solely on screening or SUD diagnosis,
16 and emphasizing that screening should be done in partnership with pregnant people.²⁵ Further, the
17 committee recommendations address clinical practices for chronic pain management,
18 pharmacotherapy, monitoring infants for neonatal abstinence syndrome, opioid prescriptions during
19 pregnancy, breastfeeding, postpartum supportive services, and the integration of contraceptive
20 counseling into SUD treatment for people of reproductive age.²⁵

21
22 In 2020 the U.S Preventive Services Task Force (USPSTF) updated their 2008 recommendation on
23 screening for unhealthy drug use for adults and adolescents, conducting two commissioned reviews
24 of the evidence on screening (i.e., asking questions about unhealthy drug use). Unhealthy drug use
25 is defined as “the use of illegal drugs and the nonmedical use of prescription psychoactive
26 medications (i.e., use of medications for reasons, for duration, in amounts, or with frequency other
27 than prescribed or use by persons other than the prescribed individual,” this definition does not
28 include alcohol or tobacco products.²⁷ The USPSTF concluded that there is insufficient evidence to
29 assess the balance of benefits and harms of screening for unhealthy drug use in adolescents.
30 However, for adults 18 years and older, the USPSTF denoted a B grade recommendation,
31 concluding that screening has a moderate net benefit when services for accurate diagnosis, effective
32 treatment, and appropriate care can be offered or referred.²⁷

33
34 Of the 30 identified screening tools many had a sensitivity of 75 percent for detecting unhealthy
35 drug use, misuse, dependence, or use disorders.²⁷ In this recommendation there are no tools
36 suggested for screening during pregnancy, with the USPSTF only reviewing 12 studies that
37 assessed the accuracy of 15 screening tools in nonpregnant people.²⁷ The majority of studies had
38 varying definitions of the reference standard (i.e., drug use, misuse, abuse, dependence, and
39 disorders) and no studies directly addressed the benefits or harms of screening on reducing drug
40 use, drug-related health, social, or legal outcomes in adults or adolescents.²⁷ Lastly, the USPSTF
41 noted several areas where further research is needed to develop recommendations. These include
42 the effectiveness of screening in adolescents; optimal screening intervals; accuracy of screening
43 tools; harms associated with punitive screening results; and strategies to improve access to
44 pharmacotherapy and psychosocial interventions.²⁷

45
46 The USPSTF commissioned two systematic reviews to evaluate the potential benefits and harms of
47 substance use screening, psychosocial interventions, pharmacotherapy, and the accuracy of
48 screening tools.²⁸ They found that despite the availability of validated screening tools, there are no
49 direct studies on the benefits or harms of universal screening for adults or adolescents.²⁸
50 Psychosocial and pharmacotherapy interventions often do not show statistically significant
51 improvement for screen-identified populations, except for those with OUD seeking treatment.²⁸

1 While physicians are crucial in addressing SUD, universal screening may not be justified without
2 sufficient evidence for its benefits across all types of unhealthy drug use due to the lack of
3 available treatment and local resources.²⁸ Physicians must carefully consider the consequences of
4 screening in their clinical setting and the availability of treatment resources before implementing
5 screening programs for SUDs. An examination conducted through a systematic review of research
6 on involuntary substance use treatment revealed no evidence supporting the benefits of this practice
7 and underscored a clear potential for harm.²⁹

8
9 Overall, available medical society and health care organization statements regarding the efficacy of
10 universal screening are mixed. While the Substance Abuse and Mental Health Services
11 Administration recommends universal screening during pregnancy as a part of SBIRT in routine
12 health care settings, the U.S. Department of Defense, Veterans Affairs, and the American Academy
13 of Family Physicians indicate that evidence is insufficient to recommend routine screening for
14 illicit drug use.^{27,29-32} Additionally, the American Psychiatric Association position statement
15 advocates for health care professionals to implement universal evidence-based screening methods
16 for substance use and co-occurring mental health disorders among pregnant and lactating women,
17 ensuring consistency and non-discrimination.³³ Screening during pregnancy should aim to enhance
18 access to evidence-based treatment for substance use, as well as optimize medical, obstetric, and
19 psychiatric care; emphasizing that screening should not be punitive in nature.³³ Thus, consensus
20 regarding universal screening for substance use during pregnancy varies and depends on the patient
21 subpopulation.

22 23 *Substance Use in Pregnancy and Reporting Implications*

24
25 The Child Abuse Prevention and Treatment Act initially enacted in 1974 and updated with the
26 Comprehensive Addiction Recovery Act in 2016 (CAPTA/CARA), is a federal law that mandates
27 the establishment of Plans of Safe Care to ensure the well-being and safety of newborns affected
28 by substance use, as well as their families or caregivers.³⁴ While physicians must notify the state
29 when a newborn has been exposed to substances per CAPTA/CARA, they are not required to file a
30 report of suspected child abuse or neglect unless stipulated by state law.³⁵ The notification
31 requirement necessitates the submission of deidentified, aggregate data on the number of children
32 falling within relevant categories.³⁶ Research shows that over 80 percent of health care
33 professionals are not familiar with CAPTA/CARA.³⁷ Even though the notification requirement
34 itself does not mandate the inclusion of patient-identifying information, there can still be adverse
35 consequences for the parent-infant dyad.³⁶

36
37 Beyond federal standards, many states have implemented additional notification and reporting
38 requirements for substance use in pregnancy. Twenty-four states and the District of Columbia (DC)
39 have passed laws classifying prenatal drug use as child abuse or neglect. Thirty-seven states and
40 DC mandate reporting of “suspected” prenatal drug use to the state.³⁸ “Suspected” drug use
41 involves assumptions or indications based on behavior or symptoms, whereas confirmatory
42 laboratory results directly detect the presence of drugs in the body through analytical testing. Some
43 states go further by requiring health care professionals to conduct prenatal substance use tests if
44 they suspect substance use.¹⁶ These measures compel health care professionals to report pregnant
45 or postpartum individuals for alleged child abuse, in some states this includes receiving MOUD.
46 Additionally, certain states have enacted legislation aimed at prosecuting pregnant individuals who
47 use substances. This legislation usually involves labeling such behavior as fetal assault, chemical
48 endangerment, and even murder.³⁹ The consequences of these laws and reports can be profound,
49 including resulting in family separation, arrests, criminal charges, and incarceration, creating a
50 cascade of adverse health outcomes that extend beyond the parent and infant. State-level policies
51 concerning child abuse and mandatory reporting are associated with reduced utilization of prenatal

1 and postpartum care among women who engage in substance use during pregnancy.⁴⁰ More
2 information is needed regarding the health outcomes and equity implications related to these
3 reporting laws. To alleviate potential adverse effects, including legal consequences tied to inquiring
4 about substance use and documenting and reporting responses, clinicians should be well-versed in
5 state requirements and adhere to best practices regarding informed consent for screening, recording
6 screening results in medical records, reporting results to medico-legal authorities, and ensuring
7 confidentiality protection.⁴¹

8 9 *Challenges in Universal Screening*

10
11 Physician confidence in conducting screening and brief interventions with pregnant patients varies.
12 A survey of 1,500 U.S. adult medicine clinicians found that almost all (95 percent) of those who
13 conducted screening and brief interventions in their practice reported implementing these measures
14 with pregnant patients for alcohol use.⁴² However, less than half (46.5 percent) of these clinicians
15 felt confident in their screening practices.⁴² In a study examining patient experiences and analyzing
16 data from 103,608 people in the Pregnancy Risk Assessment Monitoring System between 2016 and
17 2018, around 95 percent of individuals reported being asked about cigarette or alcohol use during
18 prenatal care, and 80 percent reported being asked about drug use.⁴³ The study reveals disparities in
19 substance use screening during prenatal care appointments.⁴³ Further research is needed to
20 understand the impact of screening approaches on outcomes in prenatal care settings.

21
22 A 1990 study in Pinellas County, Florida found profound racial disparities in child protective
23 services (CPS) reporting during delivery against a background of universal screening for alcohol
24 and illicit drug use in public and private prenatal care.⁴⁴ Around 15 percent of both Black and
25 White mothers identified as using substances, with Black mothers exhibiting significantly higher
26 rates of entering treatment compared to White mothers.⁴⁴ Despite higher treatment rates, Black
27 mothers using substances were referred to CPS at much higher rates than their White counterparts
28 using substances.⁴⁴ The researchers wrote, “we conclude that the use of illicit drugs is common
29 among pregnant women regardless of race and socioeconomic status. If legally mandated reporting
30 is to be free of racial or economic bias, it must be based on objective medical criteria.”⁴⁴ A 2012
31 article that drew heavily on the Florida study showed that, despite nearly universal screening for
32 prenatal drug use among Medicaid patients in one California county, and similar results among
33 racial groups enrolled in Medicaid, overall CPS referrals for Black mothers occurred at nearly four
34 times the rate of White mothers.¹⁵ The authors caution that we cannot count on universal screening
35 to promote equity, either through making referrals more objective or through improved treatment
36 participation rates.¹⁵

37
38 Lastly, in a study examining primary care physicians' implementation of screening, several barriers
39 were identified.⁴⁵ Time constraints, challenges related to parental involvement (for adolescents),
40 perceived ineffectiveness of brief intervention services, and a lack of training in providing brief
41 intervention were among the obstacles to screening and brief intervention.⁴⁵ Physicians
42 recommended boosting screening rates through increased reimbursement and the allocation of
43 dedicated resources.⁴⁵

44 45 **AMA POLICY AND ADVOCACY**

46
47 Our AMA maintains comprehensive policies addressing substance use during pregnancy. AMA
48 Policy H-420.969, “Legal Interventions During Pregnancy,” states that criminal sanctions or civil
49 liability for harmful behavior by the pregnant woman toward her fetus are inappropriate; that
50 pregnant [people who use substances or have a substance use disorder] should be provided with
51 rehabilitative treatment appropriate to their specific physiological and psychological needs; and

1 that in order to minimize the risk of legal action by a pregnant patient or an injured fetus, the
2 physician should document medical recommendations made including the consequences of failure
3 to comply with the physician's recommendation. Policy H-420.962, "Perinatal Addiction - Issues in
4 Care and Prevention," encourages the federal government to expand funding allocated to drug
5 treatment, prevention, and education to establish and make broadly available specialized treatment
6 programs for [pregnant people with substance use disorder] and breastfeeding people wherever
7 possible.

8
9 AMA Policy H-420.950, "Substance Use Disorders During Pregnancy," reiterates our AMA's
10 support of brief interventions and referral for early comprehensive treatment using a coordinated
11 multidisciplinary approach without criminal sanctions. Additionally, this policy opposes any efforts
12 to imply that a positive verbal substance use screen, a positive toxicology test, or the diagnosis of
13 substance use disorder during pregnancy automatically represents child abuse and opposes the
14 filing of a child protective services report or the removal of infants from their mothers solely based
15 on a single positive prenatal drug screen without appropriate evaluation. Our AMA further
16 advocates for appropriate medical evaluation prior to the removal of a child and advocates that
17 state and federal child protection laws be amended so that pregnant people who use substances
18 and/or have a SUD are only reported to child welfare agencies when protective concerns are
19 identified by the clinical team, rather than through automatic or mandated reporting of all pregnant
20 people with a positive toxicology test, positive verbal substance use screen, or diagnosis of a SUD.
21 This policy position is reiterated in D-95.983, "Mandatory Drug Screening Reporting," which
22 states that our AMA will work with appropriate state and specialty medical societies and with state
23 legislative bodies to ensure that physicians not be required to report patients with [positive] urine
24 drug test results to the police; and continue to promote education of physicians regarding the
25 importance of referring patients found to have [positive] urine drug tests for appropriate medical
26 treatment.

27
28 Additionally, in 2022 our AMA and several other medical societies jointly formulated model state
29 legislation to facilitate the "enhancement of access to evidence-based, non-judgmental, and non-
30 punitive maternal treatment."⁴⁶ The proposed legislation, titled "An Act to Create and Implement
31 Family Care Plans for Infants, Children, and Families," underscores the significance of establishing
32 and defining "plans of family care."⁴⁶ These plans aim to provide "supportive care and fulfillment
33 of needs for pregnant, postpartum, and parenting individuals, newborns, children, and families."⁴⁶

34 35 CONCLUSION

36
37 In theory, universal screening for substance use in pregnancy presents a potential avenue for
38 enhancing health outcomes for pregnant individuals who use substances and their infants as well as
39 preserving the parent-infant dyad. However, amidst the backdrop of stringent state policies,
40 mandatory reporting, and obstacles in accessing evidence-based care, universal screening may have
41 unintended consequences. Additional research on the impacts of mandatory reporting laws of
42 substance use in pregnant people needs to be addressed to reduce bias, inequities in care, and fear
43 of pregnant people to access the care they need.

44 45 RECOMMENDATIONS

46
47 The Council on Science and Public Health recommends that the following be adopted, and the
48 remainder of the report be filed:

- 49
50 1. That our AMA:

51

- 1 A. Encourage ongoing research on the benefits and risks of universal screening for
2 substance use during pregnancy including the impact of mandatory reporting laws,
3 evaluation of patient outcomes, effectiveness across different age groups, optimal
4 screening intervals, equity considerations, and efficacy of different screening tools.
5
6 B. Support the development and dissemination of physician education and training on
7 federal and state laws governing mandatory notification and reporting of substance
8 use during pregnancy, and the benefits and consequences of screening
9 implementation in health care settings on a state-by-state basis. (New HOD Policy)
10
11 2. That AMA policy H-420.950, "Substance Use Disorders During Pregnancy," be amended
12 by addition and deletion to read as follows:

13 Our AMA will:

- 14 (1) support brief interventions (such as engaging a patient in a short conversation,
15 providing feedback and advice) and referral for early comprehensive treatment of pregnant
16 individuals with opioid use and opioid use disorder (including naloxone or other overdose
17 reversal medication education and distribution) using a coordinated multidisciplinary
18 approach without criminal sanctions;
19
20 (2) acknowledges the health benefits of identifying substance use during pregnancy and
21 opposes any efforts, including mandatory reporting laws, that to imply that a positive
22 verbal substance use screen, a positive toxicology test, or the diagnosis of substance use
23 disorder during pregnancy automatically represents child abuse or neglect;
24 (3) support legislative and other appropriate efforts for the expansion and improved access
25 to evidence-based treatment for substance use disorders during pregnancy;
26 (4) oppose the filing of a child protective services report or the removal of infants from
27 their ~~mothers~~ parent(s) solely based on a ~~single positive~~ prenatal drug screen and/or
28 biological test(s) for substance use without appropriate evaluation;
29 (5) advocate for appropriate medical evaluation prior to the removal of a child, which takes
30 into account (a) the desire to preserve the individual's family structure, (b) the patient's
31 treatment status, and (c) current impairment status when substance use is suspected or
32 confirmed; and
33 (6) advocate that state and federal child protection laws be amended so that pregnant
34 people with substance use and substance use disorders are only reported to child welfare
35 agencies when protective concerns are identified by the clinical team, rather than through
36 automatic or mandated reporting of all pregnant people with a positive toxicology test,
37 positive verbal substance use screen, ~~or~~ diagnosis of a substance use disorder, or use of
38 evidence-based treatments for substance use disorder. (Modify Current HOD Policy)
39
40 3. That current AMA policies H-420.969, "Legal Interventions During Pregnancy," and D-
41 95.983, "Mandatory Drug Screening Reporting" be reaffirmed. (Reaffirm HOD Policy)
42

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

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 501
(A-24)

Introduced by: Medical Student Section

Subject: Fragrance Regulation

Referred to: Reference Committee E

1 Whereas, fragrances include many contact allergens, irritants, cross-reactors, or other substance
2 or natural extract often found in personal care products, cosmetics, household products, drugs,
3 and wound care products¹⁻¹¹; and
4

5 Whereas, individuals with fragrance sensitivity experience adverse effects after exposure,
6 especially patients with allergies, asthma, eczema, lung disease, and migraine^{1,2-26}; and
7

8 Whereas, due to wide use, fragrances are the most common cause of contact allergy and lead
9 to debilitating systemic dermatologic, neurologic, and immunologic side effects¹²⁻¹⁶; and
10

11 Whereas, large surveys show that over 30% of individuals may experience fragrance sensitivity,
12 50% prefer that healthcare facilities be fragrance-free, and 7% lose workdays due to workplace
13 fragrance exposure^{1,11-14}; and
14

15 Whereas, fragranced products can lower both indoor and outdoor air quality by releasing
16 hazardous air pollutants that contribute to diseases and illness^{1,5,8,14,22}; and
17

18 Whereas, the severity of fragrance sensitivity often meets Americans with Disabilities Act (ADA)
19 criteria for a disability (“physical or mental impairment that substantially limits one or more major
20 life activities”) and may be considered an “invisible disability” (“impairment...not always obvious
21 to the onlooker”)³⁰⁻³²; and
22

23 Whereas, *Core v. Champaign County Board of County Commissioners* (2012) and *McBride v. the*
24 *City of Detroit* (2009) found that severe fragrance sensitivity can be an invisible disability, leading
25 Detroit to add a fragrance-free policy to their employee ADA handbook³³⁻³⁴; and
26

27 Whereas, fragrance-free policies are recommended by the Centers for Disease Control and
28 Prevention, the American Lung Association, and the US Department of Labor Office of Disability
29 Employment Policy and are in place in multiple healthcare facilities, workplaces, schools, and
30 other organizations across the US³⁵⁻³⁹; and
31

32 Whereas, the US Food and Drug Administration and US Consumer Product Safety Commission
33 do not currently regulate fragrances^{2,40-45}; and
34

35 Whereas, the European Union has already banned nearly 1,400 chemicals from cosmetics and
36 required premarket safety assessments, mandatory registration, and government authorization
37 for the use of certain materials, compared to only 30 chemicals in the US⁴⁶⁻⁴⁸; therefore be it

1 RESOLVED, that our American Medical Association recognize fragrance sensitivity as a
2 disability where the presence of fragranced products can limit accessibility of healthcare settings
3 (New HOD Policy); and be it further
4

5 RESOLVED, that our AMA encourage all hospitals, outpatient clinics, urgent cares, and other
6 patient care areas inclusive of medical schools to adopt a fragrance-free policy that pertains to
7 employees, patients, and visitors of any kind (New HOD Policy); and be it further
8

9 RESOLVED, that our AMA work with relevant parties to advocate for governmental regulatory
10 bodies, including but not limited to the Occupational Safety and Health Administration (OSHA),
11 the Centers for Disease Control and Prevention (CDC), and the National Institute for
12 Occupational Safety and Health (NIOSH) to recommend fragrance-free policies in all medical
13 offices, buildings, and places of patient care (Directive to Take Action); and be it further
14

15 RESOLVED, that our AMA work with relevant parties to support the appropriate labeling of
16 fragrance-containing personal care products, cosmetics, and drugs with warnings about
17 possible allergic reactions or adverse events due to the fragrance, and advocates for increased
18 categorization in the use of a “fragrance free” designation (Directive to Take Action); and be it
19 further
20

21 RESOLVED, that our AMA support increased identification of hazardous chemicals in fragrance
22 compounds, as well as research focused on fragrance sensitivity in order to remove these
23 allergens from products applied to one’s body. (New HOD Policy)
24

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

Received: 3/28/2024

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RELEVANT AMA POLICY

H-440.855 National Cosmetics Registry and Regulation

1. Our AMA: (a) supports the creation of a publicly available registry of all cosmetics and their ingredients in a manner which does not substantially affect the manufacturers' proprietary interests and (b) supports providing the Food and Drug Administration with sufficient authority to recall cosmetic products that it deems to be harmful.
2. Our AMA will monitor the progress of HR 759 (Food and Drug Administration Globalization Act of 2009) and respond as appropriate. [BOT Action in response to referred for decision Res. 907, I-09; Reaffirmed in lieu of: Res. 502, A-17]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution:502
(A-24)

Introduced by: Medical Student Section

Subject: Tribally-Directed Precision Medicine Research

Referred to: Reference Committee E

1 Whereas, an estimated 80% of data used in precision medicine is from people with European
2 ancestry, limiting generalizability of research and possibly exacerbating health inequities¹⁻⁶; and
3
4 Whereas, effects of ongoing cultural genocide and colonization increase chronic disease burden
5 and reduce quality of care for American Indian and Alaska Native (AI/AN) persons^{3,7-11}; and
6
7 Whereas, a 2021 study found that AI/AN persons are underrepresented at only 0.3% of
8 research participants while comprising 3% of the US population, while non-Hispanic whites were
9 overrepresented at 82% while comprising 59% of the US population^{2,4,6,9,12}; and
10
11 Whereas, a National Institutes of Health (NIH) report on AI/AN engagement in the All of Us
12 Research Program noted a need for comanagement of precision medicine research with AI/AN
13 communities and consideration of the distinct ethical, legal, and social contexts when engaging
14 AI/AN communities in research, including their status as political entities¹³⁻¹⁶; and
15
16 Whereas, AI/AN researchers have developed specific models to recruit AI/AN persons for
17 clinical trials that account for the complex geopolitical climates of sovereign governments that
18 extend far beyond considerations of race and ethnicity, such as the principles for engaging in
19 ethical research with Indigenous people by Claw et al. and the Circle of Trust^{9,14,17-19}; and
20
21 Whereas, the Indian Health Service does not have the resources or facilities to support
22 precision medicine research without institutional partnerships²⁰; and
23
24 Whereas, a 2022 White House Office of Science and Technology Policy memorandum
25 recognized the value of Indigenous knowledge in scientific advances and created a working
26 group to include Indigenous perspectives in federal decisions and grantmaking²¹; therefore be it
27
28 RESOLVED, that our American Medical Association support clinical funding supplements to the
29 National Institutes of Health, the U.S. Food and Drug Administration, and the Indian Health
30 Service to promote greater participation of the Indian Health Service, Tribal, and Urban Indian
31 Health Programs in clinical research. (Directive to Take Action)

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

Received: 4/5/2024

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RELEVANT AMA Policy

H-460.884 Indigenous Data Sovereignty

Our AMA: (1) recognizes that American Indian and Alaska Native (AI/AN) Tribes and Villages are sovereign governments that should be consulted before the conduct of research specific to their members, lands, and properties; (2) supports that AI/AN Tribes and Villages' Institutional Review Boards (IRBs) and research departments retain the right to oversee and regulate the collection, ownership, and management of research data with the consent of their members, and that individual members of AI/AN Tribes and Villages retain their autonomy and privacy regarding research data shared with researchers, AI/AN Tribes and Villages, and governments, consistent with existing protections under 45 CFR 46; and (3) encourages: (a) the use and regular review of data-sharing agreements for all studies between academic medical centers and AI/AN Tribes and Villages be mutually agreed upon and aligned with AI/AN Tribes' and Villages' preferences, and (b) the National Institutes of Health and other stakeholders to provide flexible funding to AI/AN Tribes and Villages for research efforts, including the creation and maintenance of IRBs. [Res. 003, I-22]

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

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

D-460.976 Genomic and Molecular-based Personalized Health Care

Our AMA will: (1) continue to recognize the need for possible adaptation of the US health care system to prospectively prevent the development of disease by ethically using genomics, proteomics, metabolomics, imaging and other advanced diagnostics, along with standardized informatics tools to develop individual risk assessments and personal health plans; (2) support studies aimed at determining the viability of prospective care models and measures that will assist in creating a stronger focus on prospective care in the US health care system; (3) support research and discussion regarding the multidimensional ethical issues related to prospective care models, such as genetic testing; (4) maintain a visible presence in genetics and molecular medicine, including web-based resources and the development of educational materials, to assist in educating physicians about relevant clinical practice issues related to genomics as they develop; and (5) promote the appropriate use of pharmacogenomics in drug development and clinical trials. [CSAPH Rep. 4, A-06; Reaffirmed: CSAPH Rep. 4, A-10; Reaffirmed: CSAPH Rep. 01, A-20]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 503
(A-24)

Introduced by: Albert L. Hsu, MD

Subject: Unregulated Hemp-Derived Intoxicating Cannabinoids, and Derived Psychoactive Cannabis Products (DPCPs)

Referred to: Reference Committee E

- 1 Whereas, hemp was taken off the controlled substances list in 2018 by the Agriculture
2 Improvement Act;^{1,2} and
3
- 4 Whereas, the 2018 Farm Bill legalized hemp but included “derivatives” and “isomers” of the
5 plant in the definition of hemp, as long as content of delta-9 THC by weight is less than 0.3%;^{1,2}
6 and
7
- 8 Whereas, since 2018, processes have been developed to chemically derive over a dozen
9 different intoxicating cannabinoids from hemp at varying potency levels;^{1,2} and
10
- 11 Whereas, the recent amplified availability and use of Hemp-Driven Intoxicating Cannabinoids
12 (e.g. delta-8 tetrahydrocannabinol (THC) and over a dozen others) pose significant health risks,
13 particularly to youth;^{1,2} and
14
- 15 Whereas, reporting of adverse reactions to consumption of products containing Hemp-Derived
16 Intoxicating Cannabinoids has increased;^{1,2} and
17
- 18 Whereas, these products are marketed progressively and assertively in eye-catching ways to
19 attract public consumption, particularly that of young consumers;^{1,2} and
20
- 21 Whereas, there are no regulations imposing age restrictions on intoxicating hemp-derived
22 products, which are widely available online and in brick-and-mortar establishments like gas
23 stations, grocery stores, and convenience stores;^{1,2} and
24
- 25 Whereas, some of these intoxicating hemp-derived products intentionally mimic commercial
26 food products that appeal to children;^{1,2} and
27
- 28 Whereas, many of these products are mislabeled, alleging inaccurate potency, and not
29 disclosing presence of combinations of intoxicating cannabinoids or other toxic byproducts or
30 contaminants;^{1,2} and
31
- 32 Whereas, direct effects of these particular cannabinoids on the body include (but are not limited
33 to): impairment of cognitive function, memory and judgment; hallucinations; anxiety; nausea,
34 vomiting; dizziness, tremor; loss of consciousness, death; dependency (and prolonged use may
35 result in dependency, leading to addiction and withdrawal symptoms);^{1,2} and
36
- 37 Whereas, “Derived Psychoactive Cannabis Products” (DPCPs) have psychoactive properties
38 similar to cannabis, but are chemically derived and not grown;² and

1 Whereas, DPCPs have been available in every state, including those that have banned Δ-8
2 THC, because the loophole allows for engineering of new DPCPs, including Δ-6 THC, Δ-10
3 THC, Δ-11 THC, THC-A, THC-O, THC-P, THC-V, THC-JD, PHC, HHC, HHC-P, and HXC;^{1,2}
4 and

5
6 Whereas, DPCPs are very new (unknown and unproven and uncharacterized), and we have
7 minimal data on short- and long-term risks from use;² and

8
9 Whereas, DPCP use has been associated with psychiatric, lung, chest, and heart disorders, as
10 well as injuries and poisonings;² and

11
12 Whereas, DPCPs have been consumed accidentally by children, partly due to lack of age laws
13 in many states, poor labeling, lack of childproof containers, and marketing to young people
14 (including product packaging mimicking well-known food brands that appeal to children,
15 including Cap'n Crunch, Cocoa Puffs, Froot Loops, Starbursts and Sour Patch Kids);² and

16
17 Whereas, DPCPs have been marketed in ways to attract children, such as added in candy,
18 chips, and chocolates. DPCPs are also inexpensive (sometimes < \$5) and stores are
19 disproportionately located in low-income areas;² and

20
21 Whereas, most states do not require testing for chemical contaminants, even though DPCPs
22 are commonly synthesized using hash solvents known to be hazardous to human health;² and

23
24 Whereas, potency limits are rare, despite conclusive evidence that more potent products carry
25 higher risk of harms;² and

26
27 Whereas, there is a complex interplay between the endocannabinoid system and the estrogen
28 system in the central nervous system, raising concerns about how use of these products may
29 impact fertility, pregnancy, breastfeeding, and contraception; therefore, be it

30
31 RESOLVED, that our American Medical Association work with other interested organizations to
32 increase public awareness and promote education on the dangers of Derived Psychoactive
33 Cannabis Products (DPCPs) and Hemp-Derived Intoxicating Cannabinoids (Directive to Take
34 Action); and be it further

35
36 RESOLVED, that our AMA work with other interested organizations to advocate to close the
37 loophole in the 2018 Farm bill that allows Derived Psychoactive Cannabis Products (DPCPs)
38 and Hemp-Derived Intoxicating Cannabinoids to be regulated as hemp (Directive to Take
39 Action); and be it further

40
41 RESOLVED, that our AMA work with other interested organizations to advocate for prohibition
42 of Derived Psychoactive Cannabis Products (DPCPs) and Hemp-Derived Intoxicating
43 Cannabinoids (unless and until properly tested in humans) (Directive to Take Action); and be it
44 further

45
46 RESOLVED, that our AMA work with other interested organizations to advocate for further
47 research on the health impacts of Derived Psychoactive Cannabis Products (DPCPs) and
48 Hemp-Derived Intoxicating Cannabinoids, including the potential dangers of these products to
49 children, pregnant women and other vulnerable populations (Directive to Take Action); and be it
50 further

1 RESOLVED, that our AMA report back on this issue at A-25. (Directive to Take Action)

2

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

Received: 4/23/2024

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Relevant AMA policy:

Regulation of Cannabidiol Products H-120.926

Our AMA will: (1) encourage state controlled substance authorities, boards of pharmacy, and legislative bodies to take the necessary steps including regulation and legislation to reschedule U.S. Food and Drug Administration (FDA)-approved cannabidiol products, or make any other necessary regulatory or legislative change, as expeditiously as possible so that they will be available to patients immediately after approval by the FDA and rescheduling by the U.S. Drug Enforcement Administration; (2) advocate that an FDA-approved cannabidiol medication should be governed only by the federal and state regulatory provisions that apply to other prescription-only products, such as dispensing through pharmacies, rather than by these various state laws applicable to unapproved **cannabis** products; and (3) support

comprehensive FDA regulation of cannabidiol products and practices necessary to ensure product quality, including identity, purity, and potency.

Cannabis Product Safety D-95.956

Our American Medical Association will draft state model legislation to help states implement the provisions of AMA policies H-95.924, **Cannabis** Legalization for Adult Use and H-95.936, **Cannabis** Warnings for Pregnant and Breastfeeding Women that currently do not have such model language, including regulation of retail sales, marketing and promotion (especially those aimed at children), misleading health claims, and product labeling regarding dangers of use during pregnancy and breastfeeding.

Marketing Guardrails for the "Over-Medicalization" of Cannabis Use D-95.958

Our AMA will: (1) send a formal letter to the Food and Drug Administration and Federal Trade Commission requesting more direct oversight of the marketing of **cannabis** for medical use; (2) generate a formal letter for use by state medical societies requesting more direct oversight by state government of the marketing of **cannabis**; (3) support and encourage federal, state, and private sector research on the effects of **cannabis** marketing to identify best practices in protecting vulnerable populations, as well as the benefits of safety campaigns such as preventing impaired driving or dangerous use; (4) encourage state regulatory bodies to enforce **cannabis**-related marketing laws and to publicize and make publicly available the results of such enforcement activities; (5) encourage social media platforms to set a threshold age of 21 years for exposure to **cannabis** advertising and marketing and improve age verification practices on social media platforms; (6) encourage regulatory agencies to research how marketing best practices learned from tobacco and alcohol policies can be adopted or applied to **cannabis** marketing; and (7) support using existing AMA channels to educate physicians and the public on the health risks of **cannabis** to children and potential health risks of **cannabis** to people who are pregnant or lactating.

Cannabis Warnings for Pregnant and Breastfeeding Women H-95.936

Our AMA advocates for regulations requiring point-of-sale warnings and product labeling for **cannabis** and **cannabis**-based products regarding the potential dangers of use during pregnancy and breastfeeding wherever these products are sold or distributed.

Taxes on Cannabis Products H-95.923

Our AMA encourages states and territories to allocate a substantial portion of their **cannabis** tax revenue for public health purposes, including: substance abuse prevention and treatment programs, **cannabis**-related educational campaigns, scientifically rigorous research on the health effects of **cannabis**, and public health surveillance efforts.

Cannabis and Cannabinoid Research H-95.952

1. Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.
2. Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical **cannabis** programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of **cannabis** meets the current standards for a prescription drug product.
3. Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving **cannabis** and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for **cannabis** clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of **cannabis** for clinical research purposes; c) confirming that **cannabis** of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support.

4. Our AMA supports research to determine the consequences of long-term **cannabis** use, especially among youth, adolescents, pregnant women, and women who are breastfeeding.
5. Our AMA urges legislatures to delay initiating the legalization of **cannabis** for recreational use until further research is completed on the public health, medical, economic, and social consequences of its use.
6. Our AMA will advocate for urgent regulatory and legislative changes necessary to fund and perform research related to **cannabis** and cannabinoids.
7. Our AMA will create a **Cannabis** Task Force to evaluate and disseminate relevant scientific evidence to health care providers and the public.

Cannabis Legalization for Adult Use (commonly referred to as recreational use) H-95.924

Our AMA: (1) believes that **cannabis** is a dangerous drug and as such is a serious public health concern; (2) believes that the sale of **cannabis** for adult use should not be legalized (with adult defined for these purposes as age 21 and older); (3) discourages **cannabis** use, especially by persons vulnerable to the drug's effects and in high-risk populations such as youth, pregnant women, and women who are breastfeeding; (4) believes states that have already legalized **cannabis** (for medical or adult use or both) should be required to take steps to regulate the product effectively in order to protect public health and safety including but not limited to: regulating retail sales, marketing, and promotion intended to encourage use; limiting the potency of **cannabis** extracts and concentrates; requiring packaging to convey meaningful and easily understood units of consumption, and requiring that for commercially available edibles, packaging must be child-resistant and come with messaging about the hazards about unintentional ingestion in children and youth; (5) laws and regulations related to legalized **cannabis** use should consistently be evaluated to determine their effectiveness; (6) encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of **cannabis**, especially emergency department visits and hospitalizations, impaired driving, workplace impairment and worker-related injury and safety, and prevalence of psychiatric and addictive disorders, including **cannabis** use disorder; (7) supports public health based strategies, rather than incarceration, in the handling of individuals possessing **cannabis** for personal use; (8) encourages research on the impact of legalization and decriminalization of **cannabis** in an effort to promote public health and public safety; (9) encourages dissemination of information on the public health impact of legalization and decriminalization of **cannabis**; (10) will advocate for stronger public health messaging on the health effects of **cannabis** and cannabinoid inhalation and ingestion, with an emphasis on reducing initiation and frequency of **cannabis** use among adolescents, especially high potency products; use among women who are pregnant or contemplating pregnancy; and avoiding **cannabis**-impaired driving; (11) supports social equity programs to address the impacts of **cannabis** prohibition and enforcement policies that have disproportionately impacted marginalized and minoritized communities; and (12) will coordinate with other health organizations to develop resources on the impact of **cannabis** on human health and on methods for counseling and educating patients on the use **cannabis** and cannabinoids.

Cannabis Legalization for Medicinal Use D-95.969

Our AMA: (1) believes that scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential **cannabis** products for medical use; (2) believes that **cannabis** for medicinal use should not be legalized through the state legislative, ballot initiative, or referendum process; (3) will develop model legislation requiring the following warning on all **cannabis** products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. This product has not been approved by the Food and Drug Administration for preventing or treating any disease process."; (4) supports legislation ensuring or providing immunity against federal prosecution for physicians who certify that a patient has an approved medical condition or recommend **cannabis** in accordance with their state's laws; (5) believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions; (6) will, when necessary and prudent, seek clarification from the United States Justice Department (DOJ) about possible federal prosecution of physicians who participate in a state operated marijuana program for medical use and based on that clarification, ask the DOJ to provide federal guidance to physicians; and (7) encourages hospitals and health systems to: (a) not recommend patient use of non-FDA approved **cannabis** or **cannabis** derived products within healthcare facilities until such time as federal laws or regulations permit its use; and (b) educate medical staffs on **cannabis** use, effects and **cannabis** withdrawal syndrome.

Medical Marijuana License Safety D-95.959

1. Our AMA supports efforts to include medical **cannabis** license certification in states' prescription drug monitoring programs when consistent with AMA principles safeguarding patient privacy and confidentiality.
2. Our AMA will continue its monitoring of state legislation relating to the inclusion of **cannabis** and related information in state PDMPs.
3. Our AMA will review existing state laws that require information about medical **cannabis** to be shared with or entered into a state prescription drug monitoring program. The review should address impacts on patients, physicians and availability of information including types, forms, THC concentration, quantity, recommended usage, and other medical **cannabis** details that may be available from a dispensary.

Cannabis Intoxication as a Criminal Defense H-95.997

Our AMA believes a plea of **cannabis** intoxication not be a defense in any criminal proceedings.

Expungement, Destruction, and Sealing of Criminal Records for Legal Offenses Related to Cannabis Use or Possession H-95.910

1. Our AMA supports automatic expungement, sealing, and similar efforts regarding an arrest or conviction for a cannabis-related offense for use or possession that would be legal or decriminalized under subsequent state legalization or decriminalization of adult use or medicinal cannabis.
2. Our AMA supports automatic expungement, sealing, and similar efforts regarding an arrest or conviction of a cannabis-related offense for use or possession for a minor upon the minor reaching the age of majority.
3. Our AMA will inquire to the Association of American Medical Colleges, Accreditation Council for Graduate Medical Education, Federation of State Medical Boards, and other relevant medical education and licensing authorities, as to the effects of disclosure of a cannabis related offense on a medical school, residency, or licensing application.
4. Our AMA supports ending conditions such as parole, probation, or other court-required supervision because of a cannabis-related offense for use or possession that would be legal or decriminalized under subsequent state legalization or decriminalization of adult use or medicinal cannabis.

Preventing the Elimination of Cannabis from Occupational and Municipal Drug Testing Programs H-95.902

Our American Medical Association supports the continued inclusion of **cannabis** metabolite analysis in relevant drug testing analysis performed for occupational and municipal purposes (pre-employment, post-accident, random and for-cause).

Alcohol and Drug Use and Addiction Education H-170.992

Our AMA: (1) supports continued encouragement for increased educational programs relating to use of and addiction involving alcohol, **cannabis** and controlled substances; (2) supports the implementation of alcohol and **cannabis** education in comprehensive health education curricula, kindergarten through grade twelve; and (3) encourages state medical societies to work with the appropriate agencies to develop a state-funded educational campaign to counteract pressures on young people to use alcohol, **cannabis** products, and controlled substances.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 504
(A-24)

Introduced by: California

Subject: FDA Regulation of Biosimilars

Referred to: Reference Committee E

1 Whereas, biologics drugs account for 2% of pharmaceutical prescriptions by volume, but
2 account for 37-43% of current U.S. pharmaceutical spending and 90% of net pharmaceutical
3 spending growth over the past decade;¹⁻⁶ and
4

5 Whereas, biologic drugs, typically recombinant proteins or monoclonal antibodies, are
6 significantly more expensive than small molecule drugs; prices average ~\$10,000-\$40,000 per
7 patient per year, and can be as costly as \$250,000 per patient per year;¹⁻⁶ and
8

9 Whereas, biosimilar medications are defined by the Food and Drug Administration (FDA) and
10 European Medicines Agency (EMA) as “highly similar to and have no clinically meaningful
11 differences in terms of safety, purity, and potency when compared to an originator biologic that
12 is already approved;”⁷ and
13

14 Whereas, under the 2010 Biologics and Price Competition Act, the FDA created a licensure
15 pathway (called the 351(k) pathway) for approving biosimilars of originator biologics; the first
16 biosimilar was approved by the FDA in 2015;⁷ and
17

18 Whereas, the approval process is more stringent for a biosimilar in comparison with a generic
19 small molecule, requiring approval through the Biologics License Application Pathway and post-
20 marketing surveillance;⁸ and
21

22 Whereas, in 2018, the FDA standardized requirements for approving “interchangeable
23 biologics”, defined as a biosimilar that meets additional requirements that allow it to be
24 substituted for an originator biologic without the intervention of the health care professional who
25 prescribed the reference product, much like how generic drugs are routinely substituted for
26 brand name drugs, i.e., “pharmacy-level substitution;”⁹ and
27

28 Whereas, existing regulations allow physicians to specify when a pharmacy-level substitution is
29 not clinically appropriate, such as for reasons of allergies or concern for adverse reactions to
30 inactive ingredients; and
31

32 Whereas, U.S. regulatory requirements to designate a biosimilar as ‘interchangeable’ are
33 significantly more stringent than those in Europe; to demonstrate ‘interchangeability’ the FDA
34 requires a Phase 3 switching non-inferiority trial, in which patients are repeatedly switched
35 between the biosimilar and reference biologic agent, whereas the EMA considers biosimilars as
36 ‘interchangeable’ without the need for additional crossover “switching” studies;¹⁰⁻¹⁶ and
37

38 Whereas, long-term clinical studies of biosimilars in European countries have not demonstrated
39 any notable difference in the efficacy or safety of biosimilar products relative to originators,
40 which challenges the necessity for these switching studies;¹⁵⁻¹⁶ and

1 Whereas, the FDA requirements to achieving an “interchangeable” designation in the U.S. are
2 another reason that uptake of biosimilars has been lower in the U.S. than in other Organization
3 for Economic Cooperation and Development (OECD) countries;¹⁰⁻²⁵ and
4

5 Whereas, pharmaceutical companies have made huge investments in the U.S. to market
6 biologics as superior to their biosimilar counterparts; which may explain why biosimilars only
7 have an average market penetration rate of 20%, compared with 80% in Europe;¹⁷⁻²⁵ and
8

9 Whereas, a survey of 510 U.S. community oncologists illustrated significant knowledge gaps in
10 the use of biosimilars and this translated into hesitancy in prescribing biosimilars;²⁶ and
11

12 Whereas, a recent American Society of Clinical Oncology (ASCO) policy statement recognized
13 that “biosimilars and reference products can be considered equally efficacious for the purpose
14 of inclusion in ASCO clinical practice guidelines,” regardless of its FDA designation as
15 “interchangeable”, and supports removal of this distinction;^{27,28} therefore be it
16

17 RESOLVED, that our American Medical Association recognize that, by definition, Biosimilar
18 medications are clinically equivalent to their reference Biologic and therefore do not need a
19 designation of “interchangeability;” (New HOD Policy); and be it further
20

21 RESOLVED, that our AMA support a rigorous approval process for Biosimilar medications and
22 oppose the application of the redundant designation of “interchangeability” with the reference
23 biologic drug (New HOD Policy); and it be further
24

25 RESOLVED, that AMA support the development of a model and a process for biologic and
26 biosimilar medication prescribing that protects physician decision-making when a pharmacy-
27 level substitution is not clinically appropriate (New HOD Policy); and be it further
28

29 RESOLVED, that our AMA support physician education on the clinical equivalence of
30 Biosimilars, the FDA approval process and the post-market surveillance that is required. (New
31 HOD Policy)

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

Received: 4/23/2024

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RELEVANT AMA POLICY

H-125.980 Abbreviated Pathway for Biosimilar Approval

Our AMA supports FDA implementation of the Biologics Price Competition and Innovation Act of 2009 in a manner that 1) places appropriate emphasis on promoting patient access, protecting patient safety, and preserving market competition and innovation; 2) includes planning by the FDA and the allocation of sufficient resources to ensure that physicians understand the distinctions between biosimilar products that are considered highly similar, and those that are deemed interchangeable. Focused educational activities must precede and accompany the entry of biosimilars into the U.S. market, both for physicians and patients; and 3) includes compiling and maintaining an official compendium of biosimilar products, biologic reference products, and their related interchangeable biosimilars as they are developed and approved for marketing by the FDA.

[Modified: CSAPH Rep. 4, A-14; Modified: CSAPH Rep. 1, 1-11; Reaffirmation A-11; Res. 220, A-09.]

H-125.976 Biosimilar Interchangeability Pathway

Our AMA will: (1) strongly support the pathway for demonstrating biosimilar interchangeability that was proposed in draft guidance by the FDA in 2017, including requiring manufacturers to use studies to determine whether alternating between a reference product and the proposed interchangeable biosimilar multiple times impacts the safety or efficacy of the drug; and (2) issue a request to the FDA that the agency finalize the biosimilars interchangeability pathway outlined in its draft guidance "Considerations in Demonstrating Interchangeability With a Reference Product" with all due haste, so as to allow development and designation of interchangeable biosimilars to proceed, allowing transition to an era of less expensive biologics that provide safe, effective, and accessible treatment options for patients. [Res 523, A-18]

D-125.989 Substitution of Biosimilar Medicines and Related Medical Products

Our AMA urges that State Pharmacy Practice Acts and substitution practices for biosimilars in the outpatient arena: (1) preserve physician autonomy to designate which biologic or biosimilar product is dispensed to their patients; (2) allow substitution when physicians expressly authorize substitution of an interchangeable product; (3) limit the authority of pharmacists to automatically substitute only those biosimilar products that are deemed interchangeable by the FDA. [Modified: CSAPH Rep. 4, A-14, Modified: CSAPH Rep. 1, 1-11; Res. 918, I-08]

D-330.960 Cuts in Medicare Outpatient Infusion Services

1. Our AMA will actively support efforts to seek legislation to ensure that Medicare payments for drugs fully cover the physician's acquisition, inventory and carrying cost and that Medicare payments for drug administration and related services are adequate to ensure continued patient access to outpatient infusion services.
2. Our AMA will continue strong advocacy efforts working with relevant national medical specialty societies to ensure adequate physician payment for Part B drugs and patient access to biologic and pharmacologic agents. [Reaffirmation: I-18; Reaffirmed: CMS Rep. 10, A-16; Reaffirmation A-15; Reaffirmed and Modified: CMS Rep. 3, I-08; Res. 926, I-03]

D-330.904 Opposition to the CMS Medicare Part B Drug Payment Model

1. Our AMA will request that the Centers for Medicare & Medicaid Services (CMS) withdraw the proposed Part B Drug Payment Model.
2. Our AMA will support and actively work to advance Congressional action to block the proposed Part B Drug Payment Model if CMS proceeds with the proposal.
3. Our AMA will advocate against policies that are likely to undermine access to the best course of treatment for individual patients and oppose demonstration programs that could lead to lower quality of care and do not contain mechanisms for safeguarding patients.
4. Our AMA will advocate for ensuring that CMS solicits and takes into consideration feedback from patients, physicians, advocates, or other stakeholders in a way that allows for meaningful input on any Medicare coverage or reimbursement policy that impacts patient access to medical therapies, including policies on coverage and reimbursement.
[Res. 241, A-16]

H-110.983 Medicare Part B Competitive Acquisition Program (CAP)

Our AMA will advocate that any revised Medicare Part B Competitive Acquisition Program meet the following standards to improve the value of the program by lowering the cost of drugs without undermining quality of care:

- (1) it must be genuinely voluntary and not penalize practices that choose not to participate;
- (2) it should provide supplemental payments to reimburse for costs associated with special handling and storage for Part B drugs;
- (3) it must not reduce reimbursement for services related to provision/administration of Part B drugs, and reimbursement should be indexed to an appropriate healthcare inflation rate;
- (4) it should permit flexibility such as allowing for variation in orders that may occur on the day of treatment, and allow for the use of CAP-acquired drugs at multiple office locations;
- (5) it should allow practices to choose from multiple vendors to ensure competition, and should also ensure that vendors meet appropriate safety and quality standards;
- (6) it should include robust and comprehensive patient protections which include preventing delays in treatment, helping patients find assistance or alternative payment arrangements if they cannot meet the cost-sharing responsibility, and vendors should bear the risk of non-payment of patient copayments in a way that does not penalize the physician;
- (7) it should not allow vendors to restrict patient access using utilization management policies such as step therapy; and
- (8) it should not force disruption of current systems which have evolved to ensure patient access to necessary medications.

[Reaffirmed: CMS Rep. 4, A-22; Reaffirmed: CMS Rep. 4, I-19; Res. 216, I-18]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 505
(A-24)

Introduced by: Medical Student Section

Subject: Mitigating the Harms of Colorism and Skin Bleaching Agents

Referred to: Reference Committee E

1 Whereas, colorism is defined as discrimination which treats people with lighter skin more
2 favorably than those with darker skin, including within a given racial or ethnic group,
3 distinguishing it from racism;¹⁻⁴ and
4

5 Whereas, studies associate colorism with differences in health outcomes, treatment in clinical
6 settings, income, education, housing, and marital status;¹⁻¹³ and
7

8 Whereas, due to the social value of lighter skin entrenched in colorism and the implicit
9 understanding that lighter skin tone lessens discrimination, practices such as depigmentation
10 and skin bleaching have increased;^{2,7} and
11

12 Whereas, skin bleaching or lightening aims to lighten someone's skin in either specific areas
13 ('dark spots') or their overall skin tone, with creams serving as a common agent;¹⁵⁻¹⁹ and
14

15 Whereas, some skin lightening agents are evidence-based medical treatments for
16 dermatological conditions such as pigmentation disorders, when prescribed, instructed, and
17 supervised by a physician such as a dermatologist;²⁰⁻²⁷ and
18

19 Whereas, unsupervised skin lightening is an alarming public health concern due to associated
20 adverse effects and the large global supply of unregulated products, widely available over-the-
21 counter via online shopping such as Amazon and social media such as Tik Tok;¹⁵⁻³¹ and
22

23 Whereas, the three most common components in skin lightening agents that have faced
24 scrutiny from the medical and scientific communities are hydroquinone, mercury, and topical
25 corticosteroids, with the Food and Drug Administration (FDA) listing 22 specific products
26 confirmed to have unsafe levels of hydroquinone and mercury;³²⁻⁴² and
27

28 Whereas, the FDA and other public health agencies have raised concerns about the lack of
29 effective regulation of skin lightening agents due to illegal shipments into the US, their over-the-
30 counter availability despite lack of FDA approval, and marketing and sales tactics targeting
31 communities of color, immigrants, and people with darker skin;⁴³⁻⁴⁶ and
32

33 Whereas, the Personal Care Products Safety Act and the Cosmetic Safety Enhancement Act
34 would both improve regulation of cosmetic products such as skin lightening agents by
35 increasing safety tests, verifying international suppliers, and investigating counterfeits;⁴⁷⁻⁴⁸ and
36

37 Whereas, the long history and psychological harms of colorism and the widespread pressures to
38 engage in unsupervised skin bleaching result in many individuals starting in adolescence,
39 experiencing depression due to discrimination, and wanting to "acquire beauty," "appear more

1 white or European,” enhance their social mobility or romantic life, and even “avoid police
2 encounters,” highlighting the intersecting effects of colorism and racism;^{20-27,49-53} and
3

4 Whereas, recent pieces in the *Journal of the American Academy of Dermatology* have raised
5 concern about the public health impacts of colorism and skin bleaching;⁵⁴⁻⁵⁵ and
6

7 Whereas, the international implications of the skin bleaching product market, especially for
8 communities of color and immigrants in the US, suggest the potential for partnerships at the
9 international level with the World Medical Association and other parties; therefore be it

10
11 RESOLVED, that our American Medical Association support efforts to reduce the unsupervised
12 use of skin lightening agents, especially due to colorism or social stigma, that do not limit
13 evidence-based use by qualified clinicians (New HOD Policy); and be it further
14

15 RESOLVED, that our AMA work with the World Medical Association and other interested parties
16 to mitigate the harms of colorism and unsupervised use of skin lightening agents. (Directive to
17 Take Action)
18

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

Received: 4/24/2024

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RELEVANT AMA Policy

Racism as a Public Health Threat H-65.952

1. Our AMA acknowledges that, although the primary drivers of racial health inequity are systemic and structural racism, racism and unconscious bias within medical research and health care delivery have caused and continue to cause harm to marginalized communities and society as a whole.
2. Our AMA recognizes racism, in its systemic, cultural, interpersonal, and other forms, as a serious threat to public health, to the advancement of health equity, and a barrier to appropriate medical care.
3. Our AMA encourages the development, implementation, and evaluation of undergraduate, graduate, and continuing medical education programs and curricula that engender greater understanding of: (a) the causes, influences, and effects of systemic, cultural, institutional, and interpersonal racism; and (b) how to prevent and ameliorate the health effects of racism.
4. Our AMA: (a) supports the development of policy to combat racism and its effects; and (b) encourages governmental agencies and nongovernmental organizations to increase funding for research into the epidemiology of risks and damages related to racism and how to prevent or repair them.
5. Our AMA will work to prevent and combat the influences of racism and bias in innovative health technologies. [Res. 5, I-20; Reaffirmed: Res. 013, A-22; Modified: Speakers Rep., A-22]

Representation of Dermatological Pathologies in Varying Skin Tones H-295.853

Our AMA encourages comprehensive, inclusive and equitable representation of a diverse range of skin tones in all dermatologic and other relevant medical educational resources for medical students, physicians, non-physician healthcare providers and patients. [Res. 505, I-21]

Pulse Oximetry in Patients with Pigmented Skin D-480.957

Our AMA recognizes that pulse oximeters may not accurately measure oxygen saturation in all skin tones and will continue to urge the US Food and Drug Administration to (1) ensure pulse oximeters provide accurate and reliable readings for patients with diverse degrees of skin pigmentation and (2) ensure health care personnel and the public are educated on the limitations of pulse oximeter technology so they can account for measurement error. [Res. 915, I-22]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 506
(A-24)

Introduced by: Medical Student Section

Subject: Screening for Image Manipulation in Research Publications

Referred to: Reference Committee E

1 Whereas, the scientific community has raised alarm regarding research misconduct involving
2 image manipulation, leading some journals to implement AI-based screening tools to detect
3 alterations indistinguishable to humans and sometimes themselves generated by AI;¹⁻² and
4

5 Whereas, the American Association of Cancer Research's AI-based Proofig is now used by
6 multiple journal publishers and has demonstrated improved efficacy in detecting image
7 manipulation compared to human analysts to reject publications;³⁻⁶ and
8

9 Whereas, image screening will likely lag behind advancements in image manipulation, such as
10 generative adversarial networks (GANs), a type of machine learning algorithm specifically
11 designed to deceive or evade other AI tools; and
12

13 Whereas, efforts to improve image screening tools therefore depend on as much data from
14 manipulated images as possible; therefore be it
15

16 RESOLVED, that our American Medical Association support the creation of a nationally
17 collaborative database of manipulated images from retracted publications to provide a test bank
18 for researchers developing augmented intelligence-integrated image screening tools. (New
19 HOD Policy)
20

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

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RELEVANT AMA Policy

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.

AMA Principles of Medical Ethics: I,III,V [Issued: 2016]

Fraud and Misrepresentation in Science H-460.972

The AMA: (1) 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) 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, and (b) multidisciplinary discussions to formulate a standardized definition of scientific fraud and misrepresentation that elaborates on unacceptable behavior; (3) supports the promotion of discussions on the peer review process and the role of the physician investigator; (4) 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; (5) supports the sharing of information about scientific misconduct among institutions, funding agencies, professional societies, and biomedical research journals; and (6) 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. [CSA Rep. F, I-88; Reaffirmed: Sunset Report, I-98; Reaffirmation I-03; Appended: Res. 311, A-11; Reaffirmed: CEJA Rep. 1, A-21]

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

Our American Medical Association will: (1) 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) work with the federal government and other appropriate organizations to protect patients from false or misleading AI-generated medical advice; (3) encourage physicians to educate our patients about the benefits and risks of consumers facing LLMs including GPTs; and (4) 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. [Res. 247, A-23]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 507
(A-24)

Introduced by: Illinois

Subject: Ban on Dual Ownership, Investment, Marketing or Distribution of
Recreational Cannabis by Medical Cannabis Companies

Referred to: Reference Committee E

1 Whereas, recreational cannabis legislation is often linked to perceived medical cannabis
2 acceptance. As the industry matures, there is significantly less time from when medical
3 cannabis is first legalized, to the first recreational sale. According to Marijuana Business
4 Daily, California took 7,308 days from medical to recreational to the state's first sale.
5 Massachusetts took just 1,463 days (<https://mjbizdaily.com/letter-of-the-law/> also see
6 reference 9); and
7

8 Whereas, national recreational cannabis sales account for over 60% of all legal cannabis
9 sales (and increasing) in 2020 ([https://mjbizdaily.com/chart-nationwide-sales-of-adult-use-
10 cannabis-further-eclipse-those-of-medical-marijuana/](https://mjbizdaily.com/chart-nationwide-sales-of-adult-use-cannabis-further-eclipse-those-of-medical-marijuana/)) with medical cannabis sales either
11 plateauing or declining; and
12

13 Whereas, national recreational cannabis sales are projected to account for approximately
14 75% of all legal retail cannabis sales in 2028 ([https://mjbizdaily.com/us-cannabis-sales-
15 estimates/](https://mjbizdaily.com/us-cannabis-sales-estimates/)); and
16

17 Whereas, for example, the number of medical cannabis patients in Oregon has been in a
18 freefall since adult-use cannabis sales began, down 65% from October 2015 to July 2019
19 ([https://mjbizdaily.com/chart-how-medical-cannabis-programs-fare-in-states-with-
20 recreational-markets/](https://mjbizdaily.com/chart-how-medical-cannabis-programs-fare-in-states-with-recreational-markets/)); and
21

22 Whereas, according to Americans for Safe Access (ASA): “After combing through thousands
23 of data points on the state programs, it is clear that, with a few exceptions, states that have
24 added recreational/adult-use markets are forgetting the needs of patients”
25 (<https://www.safeaccessnow.org/sos22>); and
26

27 Whereas, ASA concludes that medical cannabis companies are moving to recreational use;
28 and
29

30 Whereas, cannabis companies are broadening their offering to get a piece of both the
31 medical and recreational pie ([https://www.adweek.com/brand-marketing/marketing-cannabis-
32 within-the-confines-of-recreational-and-medical/](https://www.adweek.com/brand-marketing/marketing-cannabis-within-the-confines-of-recreational-and-medical/)); and
33

34 Whereas, a recent JAMA study noted that as “Cannabis legalization is expanding, making
35 understanding how cannabis companies legitimize themselves critical. Industry motivation to
36 increase consumption makes policies difficult to modify once established. Public health
37 actors have been wary of industry CSR activities, given research demonstrating such
38 programs are ineffectual by design and advance corporate interest;” and

1 Whereas, similar to tobacco companies, cannabis companies appear to use corporate social
2 responsibility (CSR) practices activities that normalize and legitimize the industry for the goal
3 to open markets and influence regulation (Wakefield T, Glantz SA, Apollonio DE. Content
4 Analysis of the Corporate Social Responsibility Practices of 9 Major Cannabis Companies in
5 Canada and the US. JAMA Network Open. 2022;5(8): e2228088.
6 doi:10.1001/jamanetworkopen.2022.28088); and
7

8 Whereas, industry motivation to increase consumption makes policies difficult to modify once
9 established (Room R, Cisneros Örnberg J. Government monopoly as an instrument for
10 public health and welfare: lessons for cannabis from experience with alcohol monopolies. Int
11 J Drug Policy. 2019;74:223-228. doi:10.1016/j.drugpo.2019.10.008); and
12

13 Whereas, there is volatility in the cannabis industry: In 2021, there were around 306 merger
14 and acquisition deals in the cannabis industry across North America, more than triple the
15 number in the previous year ([https://www.statista.com/statistics/1336787/mergers-and-
16 acquisitions-cannabis-industry-north-america/](https://www.statista.com/statistics/1336787/mergers-and-acquisitions-cannabis-industry-north-america/)); and
17

18 Whereas, if any traditional medical pharmaceutical company owned, invested, promoted or
19 distributed their addictive medication for recreational purposes (even indirectly), severe
20 criticism and ethical questions would ensue; and
21

22 Whereas, in Maryland, medical cannabis companies are prohibited from selling a controlling
23 interest within five years after converting to adult-use sales
24 ([https://mmcc.maryland.gov/Documents/2023%20 PDF Files/Adult-
25 Use%20Cannabis%20Legalization/COMAR%2014.17.01-.22%205.19.23 Watermarked.pdf](https://mmcc.maryland.gov/Documents/2023%20PDF%20Files/Adult-Use%20Cannabis%20Legalization/COMAR%2014.17.01-.22%205.19.23%20Watermarked.pdf));
26 and
27

28 Whereas, dual ownership of medical/recreational cannabis companies also can represent a
29 conflict of interest that can harm medical cannabis patients (i.e. diversion of cannabis
30 products when scarce to recreational dispensaries); and
31

32 Whereas, a survey by University of Chicago in 2019 found that seventy percent of those with
33 personal experience with opioid addiction say pharmaceutical firms are responsible for the
34 problem of opioid addiction, along with 59% of those without any opioid addiction among
35 their family or friends ([https://apnorc.org/projects/pharmaceutical-companies-and-drug-users-
36 most-often-blamed-for-opioid-crisis/](https://apnorc.org/projects/pharmaceutical-companies-and-drug-users-most-often-blamed-for-opioid-crisis/)); and
37

38 Whereas, initiating THC use at a potency of 12% is associated with almost a five-fold higher
39 risk for progression to cannabis use disorder symptom onset within a year; and
40

41 Whereas THC exhibits adverse cardiac, neurological and psychiatric effects (see
42 references); therefore be it
43

44 RESOLVED, that our American Medical Association support a permanent ban on medical
45 cannabis companies (and its related holding conglomerates) from owning, investing in,
46 distributing, or promoting recreational (or “adult use”) cannabis or any other activity relating
47 to recreational use of cannabis. (New HOD Policy)

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

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Relevant AMA Policy

Cannabis Legalization for Adult Use (commonly referred to as recreational use) H-95.924

Our AMA: (1) believes that cannabis is a dangerous drug and as such is a serious public health concern; (2) believes that the sale of cannabis for adult use should not be legalized (with adult defined for these purposes as age 21 and older); (3) discourages cannabis use, especially by persons vulnerable to the drug's effects and in high-risk populations such as youth, pregnant women, and women who are breastfeeding; (4) believes states that have already legalized cannabis (for medical or adult use or both) should be required to take steps to regulate the product effectively in order to protect public health and safety including but not limited to: regulating retail sales, marketing, and promotion intended to encourage use; limiting the potency of cannabis extracts and concentrates; requiring packaging to convey meaningful and easily understood units of consumption, and requiring that for commercially available edibles, packaging must be child-resistant and come with messaging about the hazards about unintentional ingestion in children and youth; (5) laws and regulations related to legalized cannabis use should consistently be evaluated to determine their effectiveness; (6) encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of cannabis, especially emergency department visits and hospitalizations, impaired driving, workplace impairment and worker-related injury and safety, and prevalence of psychiatric and addictive disorders, including cannabis use disorder; (7) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use; (8) encourages research on the impact of legalization and decriminalization of cannabis in an effort to promote public health and public safety; (9) encourages dissemination of information on the public health impact of legalization and decriminalization of cannabis; (10) will advocate for stronger public health messaging on the health effects of cannabis and cannabinoid inhalation and ingestion, with an emphasis on reducing initiation and frequency of cannabis use among adolescents, especially high potency products; use among women who are pregnant or contemplating pregnancy; and avoiding cannabis-impaired driving; (11) supports social equity programs to address the impacts of cannabis prohibition and enforcement policies that have disproportionately impacted marginalized and minoritized communities; and (12) will coordinate with other health organizations to develop resources on the impact of cannabis on human health and on methods for counseling and educating patients on the use cannabis and cannabinoids.

Marketing Guardrails for the "Over-Medicalization" of Cannabis Use D-95.958

Our AMA will: (1) send a formal letter to the Food and Drug Administration and Federal Trade Commission requesting more direct oversight of the marketing of cannabis for medical use; (2) generate a formal letter for use by state medical societies requesting more direct oversight by state government of the marketing of cannabis; and (3) study marketing practices of cannabis, cannabis products and cannabis paraphernalia that influence vulnerable populations, such as children or pregnant people.

Cannabis Legalization for Medicinal Use D-95.969

Our AMA: (1) believes that scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential cannabis products for medical use; (2) believes that cannabis for medicinal use should not be legalized through the state legislative, ballot initiative, or referendum process; (3) will develop model legislation requiring the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. This product has not been approved by the Food and Drug Administration for preventing or treating any disease process."; (4) supports legislation ensuring or providing immunity against federal prosecution for physicians who certify that a patient has an approved medical condition or recommend cannabis in accordance with their state's laws; (5) believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions; (6) will, when necessary and prudent, seek clarification from the United States Justice Department (DOJ) about possible federal prosecution of physicians who participate in a state operated marijuana program for medical use and based on that clarification, ask the DOJ to provide federal guidance to physicians; and (7) encourages hospitals and health systems to: (a) not recommend patient use of non-FDA approved cannabis or cannabis derived products within healthcare facilities until such time as federal laws or regulations permit its use; and (b) educate medical staffs on cannabis use, effects and cannabis withdrawal syndrome.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 508
(A-24)

Introduced by: Mississippi

Subject: AMA to support regulations to decrease overdoses in children due to ingestion of edible cannabis

Referred to: Reference Committee E

1 Whereas, the American Association of Poison Control Centers shows more than 7,000
2 confirmed cases of kids younger than six years old who have eaten marijuana edibles were
3 reported to the nation's poison control centers between 2017 and 2021; and
4

5 Whereas, edibles are often packaged to look like candy or cookies and children unaware of the
6 risks may find them appealing; and
7

8 Whereas, consuming too much cannabis can lead to serious health problems in children
9 including confusion, hallucinations, tachycardia and vomiting, and in severe cases children can
10 experience trouble breathing or even coma; therefore be it
11

12 RESOLVED, that our American Medical Association work with the Food and Drug
13 Administration to strengthen how marijuana manufacturers can advertise their products,
14 including regulations that ensure the packaging does not appeal to children (Directive to Take
15 Action); and be it further
16

17 RESOLVED, that our AMA propose public awareness campaigns aimed at informing the
18 general population, especially parents and guardians, about the risks associated with edible
19 cannabis and the importance of safe storage and handling (Directive to Take Action); and be it
20 further
21

22 RESOLVED, that our AMA emphasize the importance of childproof packaging for all cannabis
23 products, along with advocating for stricter regulations to enforce this requirement. (New HOD
24 Policy)
25

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

Received: 4/24/2024

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution:509
(A-24)

Introduced by: Senior Physicians Section

Subject: Addressing Sarcopenia and its Impact on Quality of Life

Referred to: Reference Committee E

1 Whereas, sarcopenia, the progressive loss of skeletal muscle mass, strength, and function
2 typically associated with aging, poses significant health challenges to the rapidly growing senior
3 population¹; and
4

5 Whereas, sarcopenia contributes to increased risk of falls, fractures, disability, decreased
6 mobility, increased cardiovascular morbidity and mortality, cognitive decline, diminished length
7 and quality of life and increased healthcare costs^{2,3,4}; and
8

9 Whereas, sarcopenia is estimated to affect 10-16% of persons worldwide, especially the elderly
10 and malnourished⁵; and
11

12 Whereas, the prevalence of sarcopenia will predictably continue to rise in the aging population,
13 necessitating proactive measure to mitigate its impact; and
14

15 Whereas, sarcopenia is a potentially modifiable, multifactorial condition influenced by factors
16 such as inadequate nutrition, sedentary lifestyle, chronic diseases, hormonal changes and
17 inflammation⁶; and
18

19 Whereas, early detection, prevention, and management strategies are crucial measures in
20 addressing sarcopenia and its adverse consequences; therefore be it
21

22 RESOLVED, that our American Medical Association collaborate with appropriate entities to
23 develop and implement educational awareness targeting healthcare professionals, caregivers,
24 and the elderly population to increase knowledge about sarcopenia, its risk factors and
25 consequences, in order to facilitate prevention, early recognition and evidence-based
26 management as a routine part of clinical practice with elderly patients (Directive to Take Action);
27 and be it further
28

29 RESOLVED, that our AMA (1) support nutritional interventions aimed at optimizing protein
30 intake, essential amino acids, and micronutrients; (2) promote regular physical activity, including
31 resistance training, aerobic exercise, and balance exercises, tailored to individual capabilities
32 and preferences (New HOD Policy); and be it further
33

34 RESOLVED, that our AMA support allocation of resources for research initiatives aimed at
35 advancing our understanding of sarcopenia, its pathophysiology, risk factors, and treatment
36 modalities (New HOD Policy); and be it further
37

38 RESOLVED, that our AMA advocate for policy changes to support reimbursement for
39 sarcopenia screening, diagnosis, and interventions (Directive to Take Action); and be it further

- 1 RESOLVED, that our AMA collaborate with all stakeholders to integrate sarcopenia prevention
2 and management into public health agendas and aging-related initiatives. (Directive to Take
3 Action)

Fiscal Note: \$101,420: Contract with third parties to develop educational content and advertise beyond standard AMA channels.

Received: 5/2/2024

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RELEVANT AMA POLICY

H-425.994 Medical Evaluations of Healthy Persons

The AMA supports the following principles of healthful living and proper medical care: (1) The periodic evaluation of healthy individuals is important for the early detection of disease and for the recognition and correction of certain risk factors that may presage disease. (2) The optimal frequency of the periodic evaluation and the procedures to be performed vary with the patient's age, socioeconomic status, heredity, and other individual factors. Nevertheless, the evaluation of a healthy person by a physician can serve as a convenient reference point for preventive services and for counseling about healthful living and known risk factors. (3) These recommendations should be modified as appropriate in terms of each person's age, sex, occupation and other characteristics. All recommendations are subject to modification, depending upon factors such as the sensitivity and specificity of available tests and the prevalence of the diseases being sought in the particular population group from which the person comes. (4) The testing of individuals and of population groups should be pursued only when adequate treatment and follow-up can be arranged for the abnormal conditions and risk factors that are identified. (5) Physicians need to improve their skills in fostering patients' good health, and in dealing with long recognized problems such as hypertension, obesity, anxiety and depression, to which could be added the excessive use of alcohol, tobacco and drugs. (6) Continued investigation is required to determine the usefulness of test procedures that may be of value in detecting disease among asymptomatic populations.

[CSA Rep. D, A-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: CSAPH Rep. 1, A-13; Reaffirmed: CMS Rep. 03, I-17]

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 510
(A-24)

Introduced by: New Jersey

Subject: Study to investigate the validity of claims made by the manufacturers of OTC Vitamins, Supplements and "Natural Cures"

Referred to: Reference Committee E

1 Whereas, over 50 billion dollars are spent every year by vulnerable patients on advertised OTC
2 vitamins, supplements, and natural health cures; and
3
4 Whereas, cures are reported for diseases and conditions such as Diabetes, Hypertension, Liver
5 Disease, Prostate, ED, Neuropathy, Arthritis, Loss of Memory, Weight loss, and even Vision
6 Problems; and
7
8 Whereas, it is illegal to make false claims on the efficacy of medications, vitamins, supplements,
9 and "natural remedies"; and
10
11 Whereas, patients are advised that they can throw away their prescribed medications; and
12
13 Whereas, they accuse the pharmaceutical industry of a conspiracy to protect their profits while
14 hiding the truth about these "Natural" cures; and
15
16 Whereas, discontinuing medication without involvement of their Physician or Health Care
17 Provider could be deleterious to the patient's health; and
18
19 Whereas, in the advertisements, there are no peer reviewed scientific evidence is provided, only
20 inferences to scientific studies done at a "prestigious" university or a scientific breakthrough
21 discovered by a well know celebrity; and
22
23 Whereas, the FDA is overwhelmed with the number of these products which seem to appear
24 daily; therefore be it
25
26 RESOLVED, that our American Medical Association study the growing problem of
27 advertisements on OTC Vitamins, Supplements, and "Natural Cures" that claim health benefits
28 and cures. With report back at A-25 (Directive to Take Action); and be it further
29
30 RESOLVED, that our AMA collaborate with all the specialties which are affected by these claims
31 and gather scientific evidence showing benefits and false claims (Directive to Take Action); and
32 be it further
33
34 RESOLVED, that our AMA request that the FDA exercise its full scope of authority to protect our
35 patients by removing all the advertisements containing false claims of medical cures. (Directive
36 to Take Action)

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

Received: 5/3/2024

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 511
(A-24)

Introduced by: New England, American Academy of Allergy, Asthma, and Immunology
(AAAAI)

Subject: National Penicillin Allergy Day and Penicillin Allergy Evaluation & Appropriate
Delabeling

Referred to: Reference Committee E

- 1 Whereas, the American Medical Association has no policy on this resolution topic; and
2
3 Whereas, National Penicillin Allergy Day is the anniversary of Dr. Alexander Fleming's discovery
4 of penicillin on September 28, 1928; and
5
6 Whereas, more than 1 in 10 US persons report a prior allergy to a penicillin antibiotic but more
7 than 9 in 10 of these individuals do not have a confirmed allergy after appropriate investigation¹;
8 and
9
10 Whereas, a penicillin allergy label is associated with adverse consequences for individuals and
11 public health, such as a higher risk of treatment failures, C. diff colitis, antibiotic resistance,
12 surgical site infections, healthcare utilization, and death²⁻⁵; and
13
14 Whereas, most penicillin allergies are side effects or low risk reactions that do not prevent safe
15 use of penicillins and other beta-lactam therapeutics^{1,6}; and
16
17 Whereas, testing for penicillin allergy is safe and may include a skin test and/or administration of
18 a penicillin dose under observation (a drug "challenge" or "test" dose)⁶; and
19
20 Whereas, history-only evaluations with improved documentation or use in clinical decision rules
21 can result in a penicillin allergy delabeling⁷⁻¹⁰; therefore be it
22
23 RESOLVED, that National Penicillin Allergy Day, September 28, be recognized by the American
24 Medical Association (New HOD Policy); and be it further
25
26 RESOLVED, that our AMA promote penicillin allergy evaluation and appropriate delabeling.
27 (New HOD Policy)
28

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

Received: 5/7/2024

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 512
(A-24)

Introduced by: New York

Subject: Opioid Overdose Reversal Agents Where AED's Are Located

Referred to: Reference Committee E

1 Whereas, the number of overdose deaths in the US has continued to rise year by year for over
2 20 years, with nearly 110,000 dying by overdose in the year 2022, and opioids such as fentanyl
3 alone or in combination with other substances involved in the majority of overdose deaths¹; and
4

5 Whereas, naloxone is a mu opioid competitive antagonist which is effective in reversing opioid
6 overdose when administered intravenously or intranasally, has no abuse potential, has few side
7 effects or adverse events when administered to someone who has overdosed, is easy to
8 administer with little training required²⁻⁶; and
9

10 Whereas, the World Health Organization and the CDC have recommended widespread
11 availability of naloxone to reverse opioid overdoses^{7,8}; and
12

13 Whereas, expansion of the availability of naloxone is not associated with compensatory
14 increases in substance use or risk taking^{9,10}; and
15

16 Whereas, one modelling study conservatively estimated that in Allegheny County,
17 Pennsylvania, 16% of naloxone administrations occur within 200 yards of an AED location¹¹;
18 which would suggest that an additional 1/7 opioid overdoses could be reversed and potential
19 lives saved; therefore be it
20

21 RESOLVED, that our American Medical Association support the expansion of naloxone
22 availability through colocation of intranasal naloxone with AEDs in public locations. (New HOD
23 Policy)

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

Received: 5/8/2024

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RELEVANT AMA POLICY

Increasing Availability of Naloxone and Other Safe and Effective Overdose Reversal Medications H-95.932

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

BOT Rep. 22, A-16 Modified: Res. 231, A-17 Modified: Speakers Rep. 01, A-17 Appended: Res. 909, I-17 Reaffirmed: BOT Rep. 17, A-18 Modified: Res. 524, A-19 Reaffirmed: BOT 09, I-19 Reaffirmed: Res. 219, A-21 Modified: Res. 505, A-23

Oppose Tracking of People who Purchase Naloxone D-120.930

Our AMA will: (1) oppose any policies, regulations, or laws that require personally identifiable information associated with naloxone prescriptions or purchases to be tracked, monitored, or utilized for non-clinical or non-public health care purposes; and (2) advocate for availability of naloxone as an over-the-counter medication.

Res. 219, A-21

Implementing Naloxone Training into the Basic Life Support (BLS) Certification Program D-130.961

Our AMA will collaborate with the American Heart Association and other interested parties to include naloxone use in training in BLS instruction.

Res. 530, A-19

Improvement in US Airlines Aircraft Emergency Kits H-45.981

1. Our AMA urges federal action to require all US air carriers to report data on in-flight medical emergencies, specific uses of in-flight medical kits and emergency lifesaving devices, and unscheduled diversions due to in-flight medical emergencies; this action should further require the Federal Aviation Administration to work with the airline industry and appropriate medical specialty societies to periodically review data on the incidence and outcomes of in-flight medical emergencies and issue recommendations regarding the contents of in-flight medical kits and the use of emergency lifesaving devices aboard commercial aircraft.

2. Our AMA will: (a) support the addition of naloxone, epinephrine auto injector and glucagon to the airline medical kit; (b) encourage airlines to voluntarily include naloxone, epinephrine auto injector and glucagon in their airline medical kits; and (c) encourage the addition of naloxone, epinephrine auto injector and glucagon to the emergency medical kits of all US airlines (14CFR Appendix A to Part 121 - First Aid Kits and Emergency Medical Kits).

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

Res. 507, A-97 Amended: CSA Rep. 3, I-99 Reaffirmed: CSAPH Rep. 1, A-09 Reaffirmed in lieu of: Res. 502, A-16 Appended: Res. 524, A-18 Modified: Res. 508, A-22

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 safe and effective overdose reversal medications 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 safe and effective overdose reversal medications and other harm reduction measures in preventing opioid and other drug-related overdose fatalities; and (d) will continue to monitor the progress of such initiatives and respond as appropriate.

2. Our AMA will: (a) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of a drug-related overdose; and (b) support the development of adjuncts and alternatives to naloxone to combat synthetic opioid-induced respiratory depression and overdose; and (c) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for a drug-related overdose.

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

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

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

6. Our AMA supports efforts to increase access to fentanyl test strips and other drug checking supplies for purposes of harm reduction.

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

Substance Use Disorders During Pregnancy H-420.950

Our AMA will:

- (1) support brief interventions (such as engaging a patient in a short conversation, providing feedback and advice) and referral for early comprehensive treatment of pregnant individuals with opioid use and opioid use disorder (including naloxone or other overdose reversal medication education and distribution) using a coordinated multidisciplinary approach without criminal sanctions;
- (2) oppose any efforts to imply that a positive verbal substance use screen, a positive toxicology test, or the diagnosis of substance use disorder during pregnancy automatically represents child abuse;
- (3) support legislative and other appropriate efforts for the expansion and improved access to evidence-based treatment for substance use disorders during pregnancy;
- (4) oppose the filing of a child protective services report or the removal of infants from their mothers solely based on a single positive prenatal drug screen without appropriate evaluation;
- (5) advocate for appropriate medical evaluation prior to the removal of a child, which takes into account (a) the desire to preserve the individual's family structure, (b) the patient's treatment status, and (c) current impairment status when substance use is suspected; and
- (6) advocate that state and federal child protection laws be amended so that pregnant people with substance use and substance use disorders are only reported to child welfare agencies when protective concerns are identified by the clinical team, rather than through automatic or mandated reporting of all pregnant people with a positive toxicology test, positive verbal substance use screen, or diagnosis of a substance use disorder.

Res. 209, A-18 Modified: Res. 520, A-19 Modified: Res. 505, A-23

Medications for Opioid Use Disorder in Correctional Facilities H-430.987

1. Our AMA endorses: (a) the medical treatment model of employing medications for opioid use disorder (OUD) as the standard of care for persons with OUD who are incarcerated; and (b) medications for persons with OUD who are incarcerated, an endorsement in collaboration with relevant organizations including but not limited to the American Society of Addiction Medicine and the American Academy of Addiction Psychiatry.
2. Our AMA advocates for legislation, standards, policies and funding that require correctional facilities to increase access to evidence-based treatment of OUD, including initiation and continuation of medications for OUD, in conjunction with psychosocial treatment when desired by the person with OUD, in correctional facilities within the United States and that this apply to all individuals who are incarcerated, including individuals who are pregnant, postpartum, or parenting.
3. Our AMA advocates for legislation, standards, policies, and funding that require correctional facilities within the United States to work in ongoing collaboration with addiction treatment physician-led teams, case managers, social workers, and pharmacies in the communities where patients, including individuals who are pregnant, postpartum, or parenting, are released to offer post-incarceration treatment plans for OUD, including education, medication for addiction treatment and counseling, and medication for preventing overdose deaths, including naloxone (or any other medication that is approved by the United States Food and Drug Administration for the treatment of an opioid overdose), and help ensure post-incarceration medical coverage and accessibility to mental health and substance use disorder treatments, that include medication and behavioral health and social supports for addiction treatment.
4. Our AMA advocates for all correctional facilities to use a validated screening tool to identify opioid withdrawal and take steps to determine potential need for treatment for OUD and opioid withdrawal syndrome for all persons upon entry.

Res. 443, A-05 Reaffirmed: CSAPH Rep. 1, A-15 Appended: Res. 223, I-17 Modified: Res. 503, A-2

American Medical Association House of Delegates

Resolution: 513
(A-24)

Introduced by: New York
Subject: Biotin Supplement Packaging Disclaimer
Referred to: Reference Committee E

1 Whereas, although the use of biotin supplementation has become widespread for its supposed
2 stimulation of hair and nail growth, there is a sparsity in the scientific data supporting these
3 claims; and

4
5 Whereas, the FDA defines the recommended daily allowance of biotin to be 30 mcg per day for
6 an adult, the majority of biotin supplement brands have daily dosages ranging between 600-
7 10,000mcg; and

8
9 Whereas, there are no apparent negative side effects to taking megadosages of biotin, there is
10 evidence supporting its interference with many laboratory tests. In particular, excess biotin
11 may cause falsely low troponin levels, resulting in missed or delayed myocardial infarction
12 diagnoses, or false thyroid function tests leading to false diagnoses of Graves' disease;
13 therefore be it

14
15 RESOLVED, that our American Medical Association support efforts to have over-the-counter
16 biotin supplements provide a clear disclaimer on the bottle that states the possibility of lab test
17 interference (New HOD Policy); and be it further

18
19 RESOLVED, that our AMA advocates for greater awareness among both patients and
20 physicians in regards to biotin megadose interference. (Directive to Take Action)

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

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