

REPORTS OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

The following reports, 1–4, were presented by Robyn F. Chatman, MD, MPH, Chair.

1. CSAPH SUNSET REVIEW OF 2009 HOUSE OF DELEGATES POLICIES

Reference committee hearing: see report of Reference Committee E.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

At its 1984 Interim Meeting, the American Medical Association (AMA) House of Delegates (HOD) established a sunset mechanism for House policies (Policy G-600.110, “Sunset Mechanism for AMA Policy”). Under this mechanism, a policy established by the HOD ceases to be viable after 10 years unless action is taken by the HOD to retain it.

The objective of the sunset mechanism is to help ensure that the AMA Policy Database is current, coherent, and relevant. By eliminating outmoded, duplicative, and inconsistent policies, the sunset mechanism contributes to the ability of the AMA to communicate and promote its policy positions. It also contributes to the efficiency and effectiveness of HOD deliberations.

At its 2012 Annual Meeting, the HOD modified Policy G-600.110 to change the process through which the policy sunset review is conducted. The process now includes the following:

(1) As the House of Delegates adopts policies, a maximum ten-year time horizon shall exist. A policy will typically sunset after ten years unless action is taken by the House of Delegates to retain it. Any action of our AMA House that reaffirms or amends an existing policy position shall reset the sunset “clock,” making the reaffirmed or amended policy viable for another 10 years. (2) In the implementation and ongoing operation of our AMA policy sunset mechanism, the following procedures shall be followed: (a) Each year, the Speakers shall provide a list of policies that are subject to review under the policy sunset mechanism; (b) Such policies shall be assigned to the appropriate AMA Councils for review; (c) Each AMA council that has been asked to review policies shall develop and submit a report to the House of Delegates identifying policies that are scheduled to sunset. (d) For each policy under review, the reviewing council can recommend one of the following actions: (i) Retain the policy; (ii) Sunset the policy; (iii) Retain part of the policy; or (iv) Reconcile the policy with more recent and like policy; (e) For each recommendation that it makes to retain a policy in any fashion, the reviewing Council shall provide a succinct, but cogent justification. (f) The Speakers shall determine the best way for the House of Delegates to handle the sunset reports. (3) Nothing in this policy shall prohibit a report to the HOD or resolution to sunset a policy earlier than its 10-year horizon if it is no longer relevant, has been superseded by a more current policy, or has been accomplished. (4) The AMA Councils and the House of Delegates should conform to the following guidelines for sunset: (a) when a policy is no longer relevant or necessary; (b) when a policy or directive has been accomplished; or (c) when the policy or directive is part of an established AMA practice that is transparent to the House and codified elsewhere such as the AMA Bylaws or the AMA House of Delegates Reference Manual: Procedures, Policies and Practices. (5) The most recent policy shall be deemed to supersede contradictory past AMA policies. (6) Sunset policies will be retained in the AMA historical archives.

In this report, the Council on Science and Public Health (CSAPH) presents its recommendations on the disposition of the HOD policies from 2009 that were assigned to it. The CSAPH’s recommendations on policies are presented in the Appendix to this report.

RECOMMENDATION

The Council on Science and Public Health recommends that the House of Delegates policies listed in the Appendix to this report be acted upon in the manner indicated and the remainder of the report be filed.

APPENDIX - Recommended Actions on 2009 House Policies and Directives

Number	Title	Recommended Action and Rationale
D-100.974	The Use of Hormones for Anti-Aging: A Review of Efficacy and Safety	Rescind. Accomplished.
D-130.968	Standards of Care During a Mass Casualty Event	Retain in part to read as follows and change to an H-policy: 1. Our American Medical Association acknowledges that, in a mass casualty event, adjustments in the current health and medical care standards may be necessary to ensure that the care provided results in saving as many lives as possible. 2. Our AMA will: (a) continue to participate with relevant stakeholders to develop and disseminate guidance on the issue of the appropriate standard of care in a mass casualty event; (b) encourage state and specialty medical societies to work with state departments of health and other stakeholders as they develop guidance on allocating scarce resources and establishing the standard of care; and (c) encourage the creation of an adequate legal framework at the local, state, and federal levels for providing health and medical care in a mass casualty situation. Citation: (BOT Rep. 2, I-09)
D-135.982	Regulation of Endocrine Disrupting Chemicals	Retain and change to H-policy.
D-135.983	Protective NAAQS Standard for Fine Particulate Matter (PM 2.5)	Rescind. Include the specific standards outlined in this directive to H-135.946, "Protective NAAQS Standard for Fine Particulate Matter (PM 2.5)".
D-150.979	Appropriate Supplementation of Vitamin D	Retain in part to read as follows and change to an H-policy: Our AMA: 1. supports continued research on vitamin D and its metabolites, particularly long-term studies that address the benefits, adverse outcomes, and potential confounders across all life stage groups; 2. will educate physicians about the evolving science of vitamin D and its impact on health and develop resources about vitamin D for patients; 3. encourages physicians to consider measuring the serum concentration of 25-hydroxyvitamin D in patients at risk of vitamin D deficiency and counsel those with deficient or insufficient levels on ways to improve their vitamin D status; and 4. will monitor the development of new dietary references intakes for vitamin D in 2010 and respond as appropriate.
D-350.990	Next Steps Following AMA Apology to African American Physicians	Retain in part to read as follows and change the title to more accurately represent the language in the policy: <u>Next Steps Following AMA Apology to African American Physicians Collaboration with the National Medical Association to Address Health Disparities</u> Our American Medical Association will continue to work with the National Medical Association on issues of common concern, that include opportunities to increase underrepresented minorities in the health care professional pipeline including leadership roles and will continue to support the Commission to End Health Care Disparities' efforts to increase the cultural competence of clinicians, and reduce health disparities. Citation: (BOT Action in response to referred for decision Res. 606, A-09)
D-440.995	Screening Nonimmigrant Visitors to the United States for Tuberculosis	Rescind. Accomplished.
D-450.968	Best Practices for Patients with Chronic Diseases	Rescind. Accomplished.
D-460.990	Science, Policy Implications, and Current AMA Position Regarding Embryonic/Pluripotent Stem Cell Research and Funding	Retain. Still relevant.

Number	Title	Recommended Action and Rationale
D-460.993	Support of Embryonic Stem Cell Research	Retain with change in title. Convert to an H policy. Support of Embryonic/Pluripotent Stem Cell Research
D-460.996	Medical Genetics	Retain. Still relevant.
D-460.999	Support for Upgrading and Expanding Medical Research Facilities	Rescind. Accomplished by 42 USC 283k(c)2.
D-480.979	Ultrasound Contrast Agents	Retain. Still relevant.
D-515.982	Promoting Physician Awareness of the Correlation Between Domestic Violence and Child Abuse	Retain. Still relevant.
D-60.973	Prevention of Underage Drinking: A Call to Stop Alcoholic Beverages with Special Appeal to Youths	Retain in part to read as follows: 1. Our AMA will advocate for a ban on the marketing of products such as flavored malt liquor beverages-aleopops , gelatin-based alcohol products, food-based alcohol products, alcohol mists, and beverages that contain alcohol and caffeine and other additives to produce alcohol energy drinks that have special appeal to youths under the age of 21 years of age. 2. Our AMA supports state and federal regulations that would reclassify Aleopops-flavored malt liquor beverages as a distilled spirit so that it can be taxed at a higher rate and cannot be advertised or sold in certain locations.
D-95.996	Consensus Statement of the Physician Leadership on National Drug Policy	Retain in part to read as follows and change to an H-policy: Our AMA endorses <u>supports</u> the 1997 Consensus Statement of the Physicians and Lawyers for Leadership on National Drug Policy as a rational approach to informing national drug policy on illegal drugs.
D-95.997	Altered Illicit Substances	Retain. Still relevant.
D-95.999	Reduction of Medical and Public Health Consequences of Drug Abuse: Update	Retain. Still relevant.
H-10.968	Public Health Impact on Railroads	Retain. Still relevant.
H-100.962	The Use of Hormones for Anti-Aging: A Review of Efficacy and Safety	Retain. Still relevant.
H-100.969	Assuring the Safety and Quality of Foreign-Produced Pharmaceuticals	Retain. Still relevant.
H-125.989	Opposition to Payment for Prescription-Switching	Retain. Still relevant.
H-135.941	Air Pollution and Public Health	Retain. Still relevant.
H-135.946	Protective NAAQS Standard for Fine Particulate Matter (PM 2.5)	Retain with the addition of the specific standards included in D-135.983, "Protective NAAQS Standard for Fine Particulate Matter (PM 2.5)." Our AMA supports more stringent air quality standards for particulate matter than those proposed by the EPA Administrator. This position is supported by several medical specialty societies. We specifically request a NAAQS that provides improved protection for our patients which includes: <u>- 12 µg/m3 for the average annual standard</u> <u>- 25 µg/m3 for the 24-hour standard</u> <u>- 99th percentile used for compliance determination</u>
H-135.979	Clean Air	Retain. Still relevant.
H-145.979	Prevention of Unintentional Shooting Deaths Among Children	Retain. Still relevant.
H-15.958	Fatigue, Sleep Disorders, and Motor Vehicle Crashes	Retain in part to read as follows: Our AMA: (1) defines <u>recognizes</u> sleepiness behind the wheel as a major public health issue and <u>continues to</u> encourage a national public education campaign by appropriate federal agencies and relevant advocacy groups; (2) recommends that the National Institutes of Health and other

Number	Title	Recommended Action and Rationale
		<p>appropriate organizations support research projects to provide more accurate data on the prevalence of sleep-related disorders in the general population and in motor vehicle drivers, and provide information on the consequences and natural history of such conditions.</p> <p>(3) recommends that the U.S. Department of Transportation (DOT) and other responsible agencies continue studies on the occurrence of highway crashes and other adverse occurrences in transportation that involve reduced operator alertness and sleep.</p> <p>(4) encourages continued collaboration between the DOT and the transportation industry to support research projects for the devising and effectiveness-testing of appropriate countermeasures against driver fatigue, including technologies for motor vehicles and the highway environment.</p> <p>(5) urges responsible federal agencies to improve enforcement of existing regulations for truck driver work periods and consecutive working hours and increase awareness of the hazards of driving while fatigued. If changes to these regulations are proposed on a medical basis, they should be justified by the findings of rigorous studies and the judgments of persons who are knowledgeable in ergonomics, occupational medicine, and industrial psychology.</p> <p>(6) recommends that physicians: (a) become knowledgeable about the diagnosis and management of sleep-related disorders; (b) investigate patient symptoms of drowsiness, wakefulness, and fatigue by inquiring about sleep and work habits and other predisposing factors when compiling patient histories; (c) inform patients about the personal and societal hazards of driving or working while fatigued and advise patients about measures they can take to prevent fatigue-related and other unintended injuries; (d) advise patients about possible medication-related effects that may impair their ability to safely operate a motor vehicle or other machinery; (e) inquire whether sleepiness and fatigue could be contributing factors in motor vehicle-related and other unintended injuries; and (f) become familiar with the laws and regulations concerning drivers and highway safety in the state(s) where they practice.</p> <p>(7) encourages all state medical associations to promote the incorporation of an educational component on the dangers of driving while sleepy in all drivers education classes (for all age groups) in each state.</p> <p>(8) recommends that states adopt regulations <u>guidelines be developed</u> for the licensing of commercial and private drivers with sleep-related and other medical disorders according to the extent to which persons afflicted with such disorders experience crashes and injuries.</p> <p>(9) reiterates its support for physicians' use of E-codes in completing emergency department and hospital records, and urges collaboration among appropriate government agencies and medical and public health organizations to improve state and national injury surveillance systems and more accurately determine the relationship of fatigue and sleep disorders to motor vehicle crashes and other unintended injuries.</p> <p>Citation: (CSA Rep. 1, A-96; Appended: Res. 418, I-99; Reaffirmed: CSAPH Rep. 1, A-09)</p>
H-15.999	Automobile Safety Standards	Retain. Still relevant.
H-150.945	Nutrition Labeling and Nutritionally Improved Menu Offerings in Fast-Food and Other Chain Restaurants	Retain. Still relevant.
H-150.952	Point-of-Sale Warning Signs Regarding Consumption of Raw Shellfish	Retain. Still relevant.
H-160.928	Drug Initiation or Modification by Pharmacists	Retain. Still relevant.
H-160.938	Disease-Specific Self-Management Programs	Retain. Still relevant.

Number	Title	Recommended Action and Rationale
H-170.962	An Updated Review of Sex Education Programs in the United States	Rescind. Covered by H-170.968, "Sexuality Education, Sexual Violence Prevention, Abstinence, and Distribution of Condoms in Schools".
H-170.977	Comprehensive Health Education	Retain in part to read as follows: (1) Educational testing to confirm understanding of health education information should be encouraged. (2) The AMA accepts the CDC guidelines on comprehensive health education. The CDC defines its concept of comprehensive school health education as follows: (a) a documented, planned, and sequential program of health education for students in grades pre - kindergarten through 12; (b) a curriculum that addresses and integrates education about a range of categorical health problems and issues (e.g., human immunodeficiency virus (HIV) infection, drug misuse abuse , drinking and driving, emotional health, environmental pollution) at developmentally appropriate ages; (c) activities to help young people develop the skills they will need to avoid: (i) behaviors that result in unintentional and intentional injuries; (ii) drug and alcohol misuse abuse ; (iii) tobacco use; (iv) sexual behaviors that result in HIV infection, other sexually transmitted diseases, and unintended pregnancies; (v) imprudent dietary patterns; and (vi) inadequate physical activity; (d) instruction provided for a prescribed amount of time at each grade level; (e) management and coordination in each school by an education professional trained to implement the program; (f) instruction from teachers who have been trained to teach the subject; (g) involvement of parents, health professionals, and other concerned community members; and (h) periodic evaluations, updating, and improvement.
H-20.896	Support of a National HIV/AIDS Strategy	Retain in part to read as follows: Our AMA supports the creation of a National HIV/AIDS strategy, and will work with the White House Office of National AIDS Policy, the Coalition for a National HIV/AIDS Strategy, and other relevant stakeholders <u>bodies</u> to develop a update and implement the National HIV/AIDS strategy.
H-245.973	Standardization of Newborn Screening Programs	Retain. Still relevant.
H-250.989	Screening Nonimmigrant Visitors to the United States for Tuberculosis	Retain with a change in title. Screening Nonimmigrant Visitors to the United States for <u>Global Tuberculosis Control</u>
H-280.952	CMS Interim Final Rule on the Use of Seclusion and Restraints	Retain. Still relevant.
H-280.959	Recycling of Nursing Home Drugs	Retain. Still relevant.
H-345.999	Statement of Principles on Mental Health	Retain in part to read as follows: (1) Tremendous strides have already been made in improving the care and treatment of the emotionally disturbed patients with psychiatric <u>illness</u> , but much remains to be done. The mental health field is vast and includes a network of factors involving the life of the individual, the community and the nation. Any program designed to combat mental <u>psychiatric</u> illness and promote mental health must, by the nature of the problems to be solved, be both ambitious and comprehensive. (2) The AMA recognizes the important stake every physician, regardless of type of practice, has in improving our mental health knowledge and resources. The physician participates in the mental health field on two levels, as an individual of science and as a citizen. The physician has much to gain from a knowledge of modern psychiatric principles and techniques, and much to contribute to the prevention, handling and management of emotional disturbances. Furthermore, as a natural community leader, the physician is in an

Number	Title	Recommended Action and Rationale
		<p>excellent position to work for and guide effective mental health programs.</p> <p>(3) The AMA will be more active in encouraging physicians to become leaders in community planning for mental health.</p> <p>(4) The AMA has a deep interest in fostering a general attitude within the profession and among the lay public more conducive to solving the many problems existing in the mental health field.</p>
H-350.958	Hispanic Population and Access to the US Healthcare System	Rescind. Policy H-160.931 Part 2 covers this topic.
H-350.959	Guiding Principles for Eliminating Racial and Ethnic Health Care Disparities	Rescind. This policy adopted the guiding principles of the Commission to End Health Care Disparities. Since the Commission no longer exists, it does not make sense to keep a policy that references their guiding principles.
H-420.971	Infant Victims of Substance Abuse	Retain. Still relevant.
H-420.974	Warnings Against Alcohol Use During Pregnancy	Retain. Still relevant.
H-440.857	Placement of Alcohol-Based Hand Sanitizer Dispensers in Highly Trafficked Areas	Retain. Still relevant.
H-440.858	Disease Transmission Via Foods: Public Health Disaster in Waiting	Retain. Still relevant.
H-440.927	Tuberculosis	<p>Retain in part to read as follows with a change in title:</p> <p><u>Tuberculosis Control Measures</u></p> <p>Public Health Policy, Compliance and Coercion: The AMA: (1) supports state and local health authorities' the initiative of public health authorities to modernize the health codes of their states on tuberculosis (TB) control programs, including specific authorization for implementation of <u>control orders</u> a Commissioner-ordered program of directly observed therapy for tuberculosis when patient compliance poses a risk to the public;</p> <p>(2) supports the view that directly observed therapy for tuberculosis <u>TB</u> for newly discharged patients from hospitals is seen as desirable routine policy for community control against the evolution of multi-drug resistant strains;</p> <p>(3) supports the view that, recognizes in cases <u>where</u> when coercive examination, evaluation, treatment or detention are deemed seen as necessary by public health authorities, each decision should be individualized and subject to due process; and</p> <p>(4) recognizes that the control of tuberculosis (TB) in the foreign-born population is critical to the elimination of TB in the United States, and supports current Centers for Disease Control and Prevention (CDC) recommendations on the prevention and control of TB among foreign-born persons.</p>
H-440.958	Universal Immunization for Hepatitis B Virus	<p>Retain in part to read as follows:</p> <p>For enhanced effectiveness in decreasing the incidence of hepatitis B in the United States, it appears to be necessary to broaden current immunization strategies. Safe and effective vaccines are available for prevention of the disease but this use is limited by cost. Eradication of the disease on a national and international basis is a definite hope, but may not be possible without the development of antiviral treatments to control or eliminate the virus in the carrier state and in infected vaccine nonresponders. Education about the disease and its transmission is an essential element for any effective program to reduce the incidence of hepatitis B. Therefore,</p> <p>(1) The AMA <u>supports</u> endorses the principle of the universal immunization with hepatitis B vaccine of all infants, adolescents, military recruits, and students entering colleges and technical schools. While the ultimate goal is the complete immunization of all these groups, the process will need to be a gradual one beginning with the immunization of high-risk groups and then the phasing in of infants,</p>

Number	Title	Recommended Action and Rationale
		<p>adolescents, and the other groups. <u>the recommendations of Advisory Committee on Immunization Practice for the prevention of Hepatitis B.</u></p> <p>(2) The AMA encourages the immunization of all students entering medical school. The costs for the immunizations should be included in the school tuition.</p> <p>(3) The Association supports the immunization of all other risk groups with special emphasis on patients attending sexually transmitted disease clinics and drug rehabilitation centers.</p> <p>(4) (3) The <u>AMA Association</u> supports the proposed regulation of OSHA requiring the vaccination of all healthcare workers at risk of hepatitis B virus infection.</p> <p>(5) (4) The <u>AMA Association</u> encourages further professional and public education on hepatitis B disease, its transmission, and prevention. Such education should include state and federal legislators and emphasize the need for funding for immunization programs. In addition, education concerning hepatitis B should be a part of every sex and AIDS education course in the nation.</p> <p>(6) The Association encourages the scientific community to intensify its efforts to find effective therapies for patients infected with hepatitis B virus.</p> <p>(7) (5) The <u>AMA Association</u> encourages the U.S. Public Health Service and the World Health Organization to develop strategies for the elimination of hepatitis B both nationally and globally.</p>
H-440.983	Update on Sexually Transmitted Infections	Retain. Still relevant.
H-45.977	Flu Protection Guidelines for Air Travel	Retain. Still relevant.
H-45.983	Medical Oxygen Therapy on Scheduled Commercial Air Service	Retain. Still relevant.
H-45.997	In-Flight Emergency Care	Retain. Still relevant.
H-450.952	Regional Input into the Accreditation Process	Retain. Still relevant.
H-460.920	Public Access to Unpublished Research Data	Retain. Still relevant.
H-460.971	Support for Training of Biomedical Scientists and Health Care Researchers	Retain. Still relevant.
H-460.976	Congressional Earmarking of Federal Research Funds	Retain. Still relevant.
H-460.977	Proposed Moratorium on New Animal Patents	Retain. Still relevant.
H-460.994	Support for Careers in Research	Retain. Still relevant.
H-460.995	Support for Careers in Research	Retain. Still relevant.
H-470.962	Cardiovascular Preparticipation Screening of Student Athletes	Retain. Still relevant.
H-470.973	Boxing as an Olympic Sport	Retain. Still relevant.
H-470.980	Hazards of Boxing	Rescind. Covered by H-470.983, "Boxing as a Health Hazard," and H-470.984, "Brain Injury in Boxing".
H-478.990	Tobacco Control Content in Electronic Health Records	Retain. Still relevant.
H-480.972	Medical Device Safety and Physician Responsibility	Retain. Still relevant.
H-495.975	Reducing Tobacco Consumption in the Territory of Guam	Rescind. AMA policy supporting tobacco taxes applies to all jurisdictions.
H-5.997	Violence Against Medical Facilities and Health Care Practitioners and Their Families	Retain. Still relevant.
H-50.979	Use of Blood Therapeutically Drawn from Hemochromatosis Patients	Retain. Still relevant.
H-515.965	Family and Intimate Partner Violence	Retain in part to read as follows:

Number	Title	Recommended Action and Rationale
		<p>(1) Our AMA believes that all forms of family and intimate partner violence (IPV) are major public health issues and urges the profession, both individually and collectively, to work with other interested parties to prevent such violence and to address the needs of <u>victims survivors</u>. Physicians have a major role in lessening the prevalence, scope and severity of child maltreatment, intimate partner violence, and elder abuse, all of which fall under the rubric of family violence. To support physicians in practice, our AMA will continue to campaign against family violence and remains open to working with all interested parties to address violence in US society. Our AMA's efforts will be guided, in part, by its Advisory Council on Family Violence.</p> <p>(2) Our AMA believes that all physicians should be trained in issues of family and intimate partner violence through undergraduate and graduate medical education as well as continuing professional development. The AMA, working with state, county and specialty medical societies as well as academic medical centers and other appropriate groups such as the Association of American Medical Colleges, should develop and disseminate model curricula on violence for incorporation into undergraduate and graduate medical education, and all parties should work for the rapid distribution and adoption of such curricula when developed. These curricula should include coverage of the diagnosis, treatment, and reporting of child maltreatment, intimate partner violence, and elder abuse and provide training on interviewing techniques, risk assessment, safety planning, and procedures for linking with resources to assist <u>victims survivors</u>. Our AMA supports the inclusion of questions on family violence issues on licensure and certification tests.</p> <p>(3) The prevalence of family violence is sufficiently high and its ongoing character is such that physicians, particularly physicians providing primary care, will encounter <u>victims survivors</u> on a regular basis. Persons in clinical settings are more likely to have experienced intimate partner and family violence than non-clinical populations. Thus, to improve clinical services as well as the public health, our AMA encourages physicians to:</p> <ul style="list-style-type: none"> (a) Routinely inquire about the family violence histories of their patients as this knowledge is essential for effective diagnosis and care; (b) Upon identifying patients currently experiencing abuse or threats from intimates, assess and discuss safety issues with the patient before he or she leaves the office, working with the patient to develop a safety or exit plan for use in an emergency situation and making appropriate referrals to address intervention and safety needs as a matter of course; (c) After diagnosing a violence-related problem, refer patients to appropriate medical or health care professionals and/or community-based trauma-specific resources as soon as possible; (d) Have written lists of resources available for <u>victims survivors</u> of violence, providing information on such matters as emergency shelter, medical assistance, mental health services, protective services and legal aid; (e) Screen patients for psychiatric sequelae of violence and make appropriate referrals for these conditions upon identifying a history of family or other interpersonal violence; (f) Become aware of local resources and referral sources that have expertise in dealing with trauma from victimization <u>IPV</u>; (g) Be alert to men presenting with injuries suffered as a result of intimate violence because these men may require intervention as either <u>victims survivors</u> or abusers themselves; (h) Give due validation to the experience of <u>IPV victimization</u> and of observed symptomatology as possible sequelae; (i) Record a patient's <u>IPV victimization</u> history, observed traumata potentially linked to the IPV victimization, and referrals made; (j) Become involved in appropriate local programs designed to prevent violence and its effects at the community level; <p>(4) Within the larger community, our AMA: (a) Urges hospitals,</p>

Number	Title	Recommended Action and Rationale
		<p>community mental health agencies, and other helping professions to develop appropriate interventions for all victims <u>survivors</u> of intimate violence. Such interventions might include individual and group counseling efforts, support groups, and shelters.</p> <p>(b) Believes it is critically important that programs be available for victims <u>survivors</u> and perpetrators of intimate violence.</p> <p>(c) Believes that state and county medical societies should convene or join state and local health departments, criminal justice and social service agencies, and local school boards to collaborate in the development and support of violence control and prevention activities.</p> <p>(5) With respect to issues of reporting, our AMA strongly supports mandatory reporting of suspected or actual child maltreatment and urges state societies to support legislation mandating physician reporting of elderly abuse in states where such legislation does not currently exist. At the same time, our AMA opposes the adoption of mandatory reporting laws for physicians treating competent, non-elderly adult victims <u>survivors</u> of intimate partner violence if the required reports identify victims <u>survivors</u>. Such laws violate basic tenets of medical ethics. If and where mandatory reporting statutes dealing with competent adults are adopted, the AMA believes the laws must incorporate provisions that: (a) do not require the inclusion of victims' <u>survivors'</u> identities;</p> <p>(b) allow competent adult victims <u>survivors</u> to opt out of the reporting system if identifiers are required;</p> <p>(c) provide that reports be made to public health agencies for surveillance purposes only;</p> <p>(d) contain a sunset mechanism; and</p> <p>(e) evaluate the efficacy of those laws. State societies are encouraged to ensure that all mandatory reporting laws contain adequate protections for the reporting physician and to educate physicians on the particulars of the laws in their states.</p> <p>(6) Substance abuse and family violence are clearly connected. For this reason, our AMA believes that: (a) Given the association between alcohol and family violence, physicians should be alert for the presence of one behavior given a diagnosis of the other. Thus, a physician with patients with alcohol problems should screen for family violence, while physicians with patients presenting with problems of physical or sexual abuse should screen for alcohol use.</p> <p>(b) Physicians should avoid the assumption that if they treat the problem of alcohol or substance use and abuse they also will be treating and possibly preventing family violence.</p> <p>(c) Physicians should be alert to the association, especially among female patients, between current alcohol or drug problems and a history of physical, emotional, or sexual abuse. The association is strong enough to warrant complete screening for past or present physical, emotional, or sexual abuse among patients who present with alcohol or drug problems.</p> <p>(d) Physicians should be informed about the possible pharmacological link between amphetamine use and human violent behavior. The suggestive evidence about barbiturates and amphetamines and violence should be followed up with more research on the possible causal connection between these drugs and violent behavior.</p> <p>(e) The notion that alcohol and controlled drugs cause violent behavior is pervasive among physicians and other health care providers. Training programs for physicians should be developed that are based on empirical data and sound theoretical formulations about the relationships among alcohol, drug use, and violence.</p>
H-55.977	Male Breast Cancer	Retain. Still relevant.

Number	Title	Recommended Action and Rationale
H-60.946	Need for Adequate Training of Teachers to Identify Potentially Dangerous Children and the Provision of Adequate Insurance Coverage to Provide for their Treatment	Retain. Still relevant.
H-90.974	Opposition to Obesity as a Disability	Retain. Still relevant.
H-95.955	Physician Impairment	Retain in part to read as follows: (1) The AMA defines physician impairment as any physical, mental or behavioral disorder that interferes with ability to engage safely in professional activities and will address all such conditions in its Physician Health Program. (2) The AMA encourages state medical society-sponsored physician health and assistance programs to take appropriate steps to address the entire range of <u>illnesses with the potential to cause</u> impairment problems that affect physicians, to develop case finding mechanisms for all types of physician impairments, and to collect data on the prevalence of conditions affecting physician health. (3) The AMA encourages additional research in the area of physician <u>illness with the potential to cause</u> impairment, particularly in the type and impact of external factors adversely affecting physicians, including workplace stress, litigation issues, and restructuring of the health care delivery systems.
H-95.962	Inhalant Abuse	Retain. Still relevant.
H-95.975	Substance Use Disorders as a Public Health Hazard	Retain. Still relevant.
H-95.976	Drug Abuse in the United States – the Next Generation	Retain in part with a change in title to read as follows: Drug Abuse in the United States – the Next Generation <u>Addiction and Unhealthy Substance Use</u> Our AMA is committed to efforts that can help <u>the</u> this national problem of <u>addiction and unhealthy substance use</u> from becoming a chronic burden. The AMA pledges its continuing involvement in programs to alert physicians and the public to the dimensions of the problem and the most promising solutions. The AMA, therefore: (1) supports cooperation in activities of organizations such as the National Association for Perinatal Addiction Research and Education (NAPARE) in fostering education, research, prevention, and treatment of substance abuse <u>addiction</u> ; (2) encourages the development of model substance abuse <u>addiction</u> treatment programs, complete with an evaluation component that is designed to meet the special needs of pregnant women and women with infant children through a comprehensive array of essential services; (3) urges physicians to routinely provide, at a minimum, a historical screen for all pregnant women, and those of childbearing age for substance abuse and to follow up positive screens with appropriate counseling, interventions and referrals; (4) supports pursuing the development of educational materials for physicians, physicians in training, other health care providers, and the public on prevention, diagnosis, and treatment of perinatal addiction. In this regard, the AMA encourages further collaboration with the Partnership for a Drug-Free America in delivering appropriate messages to health professionals and the public on the risks and ramifications of perinatal drug and alcohol use; (5) urges the National Institute on Drug Abuse, the National Institute on Alcohol Abuse and Alcoholism, and the Substance Abuse and Mental Health Services Administration Federal Office for Substance Abuse Prevention to continue to support research and demonstration projects around effective prevention and intervention strategies;

Number	Title	Recommended Action and Rationale
		(6) urges that public policy be predicated on the understanding that alcoholism and drug dependence, including tobacco dependence <u>use disorder</u> as indicated by the Surgeon General's report, are diseases characterized by compulsive use in the face of adverse consequences; (7) affirms the concept that substance abuse <u>addiction</u> is a disease and supports developing model legislation to appropriately address perinatal addiction as a disease, bearing in mind physicians' concern for the health of the mother, the fetus and resultant offspring; and (8) calls for better coordination of research, prevention, and intervention services for women and infants at risk for both HIV infection and perinatal addiction.

2. DRUG SHORTAGES: 2019 UPDATE

Informational report; no reference committee hearing.

HOUSE ACTION: FILED

INTRODUCTION

American Medical Association (AMA) Policy H-100.956, “National Drug Shortages,” directs the Council on Science and Public Health (CSAPH) to continue to evaluate the drug shortage issue and report back at least annually to the House of Delegates (HOD) on progress made in addressing drug shortages in the United States (see Appendix 1 for policy). This report provides an update on continuing trends in national drug shortages and ongoing efforts to further evaluate and address this critical public health issue.

METHODS

English-language reports were selected from a PubMed and Google Scholar search from September 2017 to February 2019, using the text term “drug shortages.” Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the US Food and Drug Administration (FDA), National Academies of Sciences, Engineering, and Medicine (NASEM), American Society of Health-System Pharmacists (ASHP), Pew Charitable Trusts, Duke Margolis Center for Health Policy, the Institute for Safe Medication Practices (ISMP), and by direct contact with key FDA, ASHP, and Utah Drug Information Service staff who monitor drug shortages and related issues daily.

BACKGROUND

The CSAPH has issued nine reports on drug shortages.¹⁻⁹ The findings and conclusions of the first five reports are summarized in CSAPH Report 2-I-15, “National Drug Shortages: Update.”⁴ The remainder of this report will update information on drug shortages since the 2018 report was developed, specifically commenting on the new initiatives to identify the root causes of drug shortages.

CURRENT TRENDS IN DRUG SHORTAGES

Drug shortages remain an ongoing public health concern in the United States. The rate of new shortages is increasing and common shortages are severely impacting patient care and pharmacy operations. Ongoing supply challenges of certain medications, typically older, generic, injectable products that are off-patent and have few suppliers (usually three or fewer), persist. Long-term active and ongoing shortages are not resolving and the most basic products required for patient care are in shortage, including bupivacaine, lidocaine, hydromorphone, morphine, fentanyl, ketamine, ondansetron, saline, and sterile water. Causes of shortages continue to remain largely unchanged and are mostly triggered by quality problems during manufacturing processes.

The two primary data sources for information on drug shortages in the United States continue to be the Drug Shortage Program at the FDA and the Drug Shortage Resource Center maintained by ASHP in cooperation with the University of Utah Drug Information Service (UUDIS). According to the most recent data compiled by ASHP and UUDIS, in

2018 there were a total of 306 active shortages, with 186 of those being new (compared to 2017 which saw 303 active and 146 new shortages). Each quarter since the third quarter of 2017 saw an increase in drug shortages. The top five classes of drugs implicated in active drug shortages include CNS medications (43); antimicrobials (33); electrolytes, nutrition, and fluids (31); cardiovascular medications (23); and chemotherapy agents (16). The reasons for drug shortages vary and unknown/unreported reasons account for 51 percent of drug shortages. Manufacturing issues account for 30 percent of shortage issues and drug discontinuation increased to 10 percent of shortage issues in 2018 compared to 4 percent in 2017. (See Appendix 2 for ASHP/UUDIS data).¹⁰

The fifth annual report on drug shortages from the FDA to Congress published in June 2018, summarizes the major actions the FDA took in calendar year 2017 related to drug shortages.¹¹ Notably, using a range of available tools, the FDA worked with manufacturers to successfully prevent 145 shortages during 2017.¹¹

The FDA continues to utilize a mobile app to provide up-to-date access to drugs in shortage as well as notifications about new and resolved drug shortages and gives physicians the ability to report a drug shortage. The FDA Drug Shortages webpage includes a current shortages list, mobile app, and additional information (Box 1).¹² The ASHP Shortage Resource Center provides a list of shortages, guidance on managing critical shortages, as well as shortage metrics (Box 1).¹³ Additionally, a recent publication details ASHP guidelines for managing drug product shortages and provides a framework for healthcare teams in patient care to develop policies and procedures that minimize the effects of drug shortages on quality of care.¹⁴

CURRENT DRUG SHORTAGE ACTIVITIES

National Academies of Sciences Engineering Medicine Workshop, Medical Product Shortages during Disasters: Opportunities to Predict, Prevent, and Respond

In September 2018, the AMA participated in a NASEM-convened workshop, Medical Product Shortages during Disasters: Opportunities to Predict, Prevent, and Respond, to better understand the gaps that lead to cascading effects in patient care throughout the U.S. health care system when shortages of medical devices, drugs, and supplies occur in the context of disaster (not day-to-day shortages).

Discussion topics included the importance of public-private partnerships and a collaborative effort; situational awareness about all elements of the supply chain; the need to identify useful metrics, collect sufficient data, and share it accordingly; the strategic national stockpile; issues with “just-in-time stocking” and shortage cascades; the issues involved in frequent staff (re)training, learning, and alert fatigue; and the impact on patient care including “regression of care” when physicians need to find solutions other than the standard of care. The detailed proceedings from the workshop have been published.¹⁵

Multi-stakeholder Summit, Drug Shortages as a Matter of National Security: Improving the Resilience of the Nation’s Healthcare Critical Infrastructure

In September 2018, the AMA participated in a summit regarding drug shortages as a matter of national security, sponsored by several stakeholders including ASHP, ISMP, the American Hospital Association, American Society of Anesthesiologists, and American Society of Clinical Oncology.

The objectives of the summit were to identify the vulnerabilities of the supply chain that result in drug shortages; define the roles and responsibilities of the public and private sectors for planning and responding to national security events; and identify recommendations to strengthen the current healthcare infrastructure to prevent drug shortages that may result in patient harm.

The meeting brought together representatives from clinician groups, industry and supply chain, and public-sector members to discuss drug shortages as a national security priority. Several recommendations were offered after the discussion as potential policy and marketplace changes that may help prevent and mitigate drug shortages.¹⁶

Some of the recommendations discussed at length included:

1. The need for greater understanding of the drug supply chain from beginning to end, including clarity of raw material sources, overall quality of production, and greater transparency from manufacturers;

2. Development of management models using data science as well as the need to identify the relevant metrics related to the drug supply chain and how to collect and share it;
3. Development of an “essential drugs” list;
4. Incentives for manufacturers;
5. Standardization of medication dose, preparations, and size.

U.S. Food and Drug Administration Activities

In a statement from July 2018, FDA Commissioner Scott Gottlieb, MD, and FDA Center for Drug Evaluation and Research Director Janet Woodcock, MD, outlined new efforts the FDA is advancing to address drug shortages – a three-pronged approach that focuses on preventing shortages, early identification of anticipated shortages, and responding to shortages using their current authorities, as well as the creation of an Interagency Drug Shortage Task Force.^{17,18}

Interagency Drug Shortage Task Force. An Interagency Drug Shortage Task Force was established by the FDA to identify the root causes of drug shortages and advance potential long-term solutions in a report to Congress. The Task Force will be led by FDA’s Associate Commissioner for Strategic Initiatives and will include federal officials from several agencies concerned with drug shortages including the FDA, the Centers for Medicare & Medicaid Services (CMS), the Office of the Assistant Secretary for Preparedness and Response, the Department of Veterans Affairs, the Department of Defense, and the Federal Trade Commission.¹⁹

Currently, in cases of drug shortages, the FDA has a variety of tools to employ to minimize the impact. These include expediting the inspection of a new drug manufacturing facility so it can become operational as soon as possible; expediting the review of a new or generic drug application that, if approved, may help mitigate or prevent a shortage; urging manufacturers of similar or alternative products to ramp up production to meet an anticipated increased demand; and exercising discretion with respect to temporary importation of a product from a foreign manufacturing source until a shortage is resolved. FDA officials have stated that the work of the Task Force will be “forward-leaning and extensive” with the goal of complementing and strengthening the ongoing efforts of the Agency to establish long-term solutions. Some of the considerations include proposals for possible additions to FDA authorities, evaluation of reimbursement policies of payors, exploration of possible incentives to encourage manufacturing that can expand and ensure a stable drug supply, evaluation of the need for an essential drugs list, and incentives for manufacturing critical drugs.

FDA Listening Session on Drug Shortages. In October 2018, the FDA held a series of invitation-only listening sessions at the FDA. Invitations were extended to a diverse group of stakeholders including medical organizations (such as AMA), pharmacies and hospitals, manufacturing groups, group purchasing organizations (GPOs) and distributors, and experts and think tanks. The goal of the sessions was for the FDA to gather information concerning the economic and clinical impact of drug shortages and to inform the newly formed Interagency Drug Shortage Task Force. AMA staff in attendance provided comprehensive comments regarding AMA policy and the most recent Council on Science and Public Health report from A-18.

The FDA lists four general themes that came from the series of listening sessions:

1. The impacts of drug shortages affect every level of the health care system, ultimately compromising the standard of care, producing waste, and increasing costs.
2. Multiple market factors such as buyer and seller consolidation, low margins, and contracting practices contribute to drug shortages.
3. It is unclear what the right level of transparency is based on manufacturing security concerns, and hospital, pharmacy, and GPO needs. The health care community would like more transparency throughout the supply chain.
4. Multiple federal agencies such as the FDA, Drug Enforcement Administration, and CMS, have different authorities on drugs, which makes it hard for both industry and hospitals to manage. Ideas have been put forth on how agencies can mitigate – but may unintentionally exacerbate – the issues.

FDA Public Meeting: Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions. In November 2018, the FDA Interagency Task Force under a cooperative agreement with the Robert J. Margolis, MD, Center for Health Policy at Duke University, hosted a public meeting for open discussion of the root causes of drug shortages

and solutions, which AMA staff attended. The speakers at the day-long public meeting included a broad range of stakeholders.

The FDA's efforts to date have addressed the immediate causes of drug shortages such as manufacturing quality issues, raw material sourcing, business decisions to discontinue products, and marketplace changes. This initiative aims to focus on identifying and remedying systemic, root causes that drive and sustain product shortages and developing enduring solutions to mitigate and prevent drug shortages from occurring.

Little consensus exists regarding the most significant and the largest contributing root causes of drug shortages. A useful discussion guide from this public meeting outlines some of the hypothesized root causes of drug shortages including lacking information to assess drug supply reliability; low profit margins, particularly among generic drugs, causing decreased production and quality; barriers to market entry from manufacturers to address shortages; and additional contributing factors including "just-in-time" manufacturing, contracts and agreements, stockpiling, and increased globalization/limited supply chain options.²⁰

Input from this meeting, as well as from listening sessions with stakeholders, and the public docket will be considered during the drafting of a report providing recommendations/guidance that the Task Force plans to submit to Congress by the end of 2019. Potential areas of action might include, but would not be limited to, contracting, tax incentives, increased transparency of manufacturing quality, reimbursement or regulatory changes, as well as any other proposed solutions as appropriate.

Public Docket. FDA had a public docket open to receive stakeholder comments regarding the root causes of drug shortages and possible solutions which closed on January 11, 2019. The AMA submitted comments to the docket outlining our policy and recommendations (Appendix 3).²¹

Quality Metrics. Appropriate quality metrics provide elements of assurance and oversight necessary for pharmaceutical manufacturing and quality control; however, the complexity of the manufacturing process makes the collection and use of metrics difficult. The FDA has taken steps within its regulatory authority to address this issue as it relates to drug shortages by developing a quality metrics program for pharmaceutical manufacturers.²² Information generated could be used by the FDA to identify drugs at greater risk of shortage and proactively reduce that risk before a disruption occurs.

Manufacturing Modernization. Another FDA initiative encourages manufacturers to adopt advanced manufacturing technologies, such as continuous manufacturing, that increase production reliability and capacity and can assist in medical product shortage mitigation. To support this initiative, the FDA established an Emerging Technology Program to foster dialogue between FDA and manufacturers as they work to develop and implement these approaches.²³ Additionally, a recent workshop at NASEM, and sponsored by the FDA and the Biomedical Advanced Research and Development Authority, focused on the status of, and research opportunities for, continuous manufacturing in the pharmaceutical industry.²⁴

Generic Drugs. As previously mentioned, medical product shortages typically involve older, generic products. In January of 2018, the FDA announced a Drug Competition Action Plan aimed at promoting competition and access, especially in the development of generic drugs in pharmaceutical categories that lack competition.²⁵

New Companies to Mitigate Drug Shortages

Civica Rx. Recently, more than 120 health organizations have been involved in the creation of a not-for-profit generic drug company, Civica Rx, that will manufacture, or sub-contract manufacturing of, critical hospital-administered drugs.²⁶ Martin VanTrieste, Civica Rx CEO, has stated that "All drug shortages are the result of economics, financial and management decisions." The organization will initially seek to stabilize the supply of essential generic medications administered in hospitals (including sterile injectables), many of which have fallen into chronic shortage situations, putting patients at risk. The organization is focusing on fair and sustainable prices for medications and predicts this initiative will ultimately result in overall lower costs and more predictable supplies of essential generic medicines. Civica Rx expects to have its first products on the market in 2019.

ProvideGx. In January 2019, Premier Inc. announced that it has formed a company intended to help address drug shortages, ProvideGx, and has partnered with five generic drug makers to address a targeted pipeline of 60 crucial drugs that will be available through Premier's GPO.

SUMMARY

The rate of new medical product shortages is increasing and shortages of essential medications are severely impacting patient care and pharmacy operations. The ongoing supply challenges of mostly generic medications, typically injectable products, that are off-patent persist.

A recent FDA data analysis of the scope and scale of drug shortages evaluated the occurrence, duration, intensity, and public health impact medical product shortages.²⁷ The analysis revealed that the occurrence of active and ongoing shortages is increasing; the duration is longer; shortages are more persistent; intensity is high, as some shortages have been ongoing for >8 years; and the public health impact is high because of an increase in patient harm and health care losses. Congruent with these findings, the FDA has undertaken new initiatives to address the systemic root causes and contributing factors that lead to shortages and determine enduring solutions. Our AMA has been involved in conversations with the FDA and other stakeholders and remains committed to addressing this critical issue. Beyond activity at the federal agency level, the marketplace in 2019 saw the emergence of two new companies, Civica Rx and ProvideGx, which may directly address shortages by bringing into the market supplies of drugs and drug vehicles critically needed by hospitals and the patients they serve.

The AMA's drug shortage policy is timely and already addresses a variety of issues that are under consideration by the FDA and other stakeholder including the improvement quality systems; expedited facility inspections and manufacturing changes/improvements; necessary resiliency and redundancy in manufacturing capability; evaluation of root causes of drug shortages; transparent analysis of economic drivers and reasonable and sustainable payment rates for prescription drugs; greater transparency of the manufacturing process; and including drug manufacturing sites as part of the nation's critical infrastructure plan. Therefore, the Council feels that an update to AMA policy is not warranted at this time.

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- <https://www.ashp.org/-/media/assets/advocacy-issues/docs/Recommendations-Drug-Shortages-as-Matter-of-Natl-Security.ashx?la=en&hash=FA494117C6255A5493F77B67EDE39DD28B790FAD>.
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Box 1. Resources available to assist in mitigation of drug shortages.

1. [ASHP Resource Center](#)
2. ASHP [list](#) of current shortages
3. ASHP and University of Utah [guidance](#) on small-volume parenteral solutions shortages
4. ASHP and University of Utah [guidance](#) on injectable opioid shortages
5. [FDA Drug Shortages Page](#) (includes current shortages list, mobile app, and additional information)

APPENDIX 1 - AMA Drug Shortage Policy

H-100.956, "National Drug Shortages"

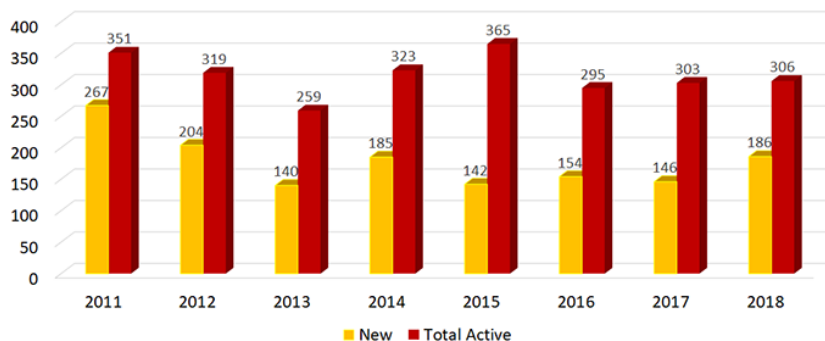
1. Our AMA considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients.
2. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.
3. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services (DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.
4. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.
5. The Council on Science and Public Health shall continue to evaluate the drug shortage issue, including the impact of group purchasing organizations on drug shortages, and report back at least annually to the House of Delegates on progress made in addressing drug shortages.
6. Our AMA urges the development of a comprehensive independent report on the root causes of drug shortages. Such an analysis should consider federal actions, the number of manufacturers, economic factors including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and pricing. In particular, further transparent analysis of economic drivers is warranted. The federal Centers for Medicare & Medicaid Services (CMS) should review and evaluate its 2003 Medicare reimbursement formula of average sales price plus 6% for unintended consequences including serving as a root cause of drug shortages.

7. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market due to compliance issues unless such removal is clearly required for significant and obvious safety reasons.
8. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history.
9. Our AMA will collaborate with medical specialty society partners and other stakeholders in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs.
10. Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to determine whether such an activity has the potential to worsen drug shortages.
11. Our AMA urges the FDA to require manufacturers to provide greater transparency regarding production locations of drugs and provide more detailed information regarding the causes and anticipated duration of drug shortages.
12. Our AMA encourages electronic health records (EHR) vendors to make changes to their systems to ease the burden of making drug product changes.
13. Our AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities.
14. Our AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan.

APPENDIX 2 - ASHP/University of Utah Drug Information Service Drug Shortage Data

Figure 1.

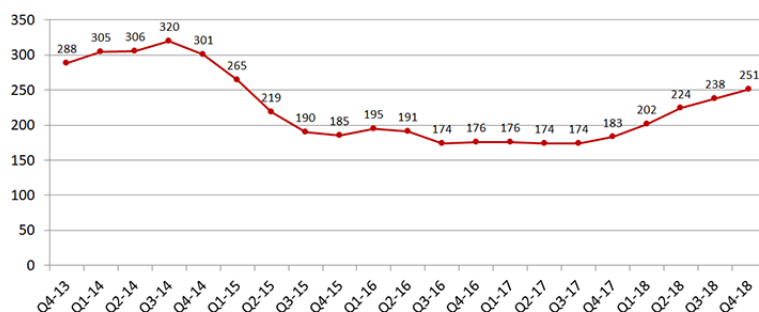
National Drug Shortages: Annual New Shortages and Total Active Shortages
2001 to 2018



University of Utah Drug Information Service
Contact: Erin.Fox@hsc.utah.edu, @foxerinr for more information.

Figure 2.

National Drug Shortages: Active Shortages by Quarter
October 1, 2013 to December 31, 2018



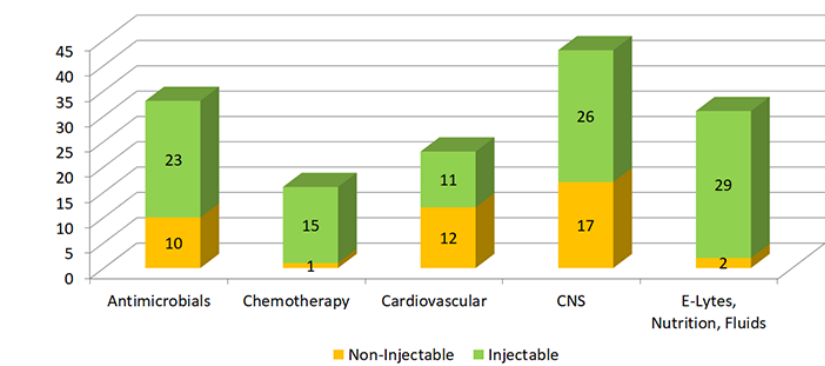
Note: These data represent the count of active shortages on the last day of each quarter, and should not be interpreted as total shortages for that period.

University of Utah Drug Information Service
Contact: Erin.Fox@hsc.utah.edu, @foxerinr for more information.

Figure 3.

National Drug Shortages: Active Shortages-Top Five Drug Classes

December 31, 2018

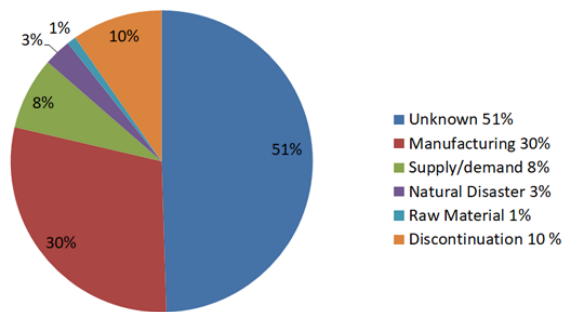


University of Utah Drug Information Service
Contact: Erin.Fox@hsc.utah.edu, [@foxeirinr](https://twitter.com/foxeirinr) for more information.

Figure 4.

National Drug Shortages

Reasons for Shortages* – 2018



*Based on information provided by manufacturers to the University of Utah Drug Information Service
University of Utah Drug Information Service
Contact: Erin.Fox@hsc.utah.edu, [@foxeirinr](https://twitter.com/foxeirinr) for more information.

APPENDIX 3 - AMA Comment Letter: Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions; Docket No. FDA-2018-N-3272

AMA
AMERICAN MEDICAL ASSOCIATION

JAMES L. MADARA, MD
EXECUTIVE VICE PRESIDENT/CEO

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January 11, 2019

The Honorable Scott Gottlieb, MD
Commissioner
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Re: Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions; Docket No. FDA-2018-N-3272

Dear Commissioner Gottlieb:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to provide comments in response to *Identifying the Root Causes of Drug Shortages and Finding Enduring Solutions*. We applaud the U.S. Food and Drug Administration's (FDA) establishment of a Drug Shortages Task Force in order to identify the root causes of drug shortages and recommend sustainable and structural policy solutions in a report to Congress. The persistence and pervasiveness of drug shortages have consequences for patient care and require an ongoing comprehensive examination of the systemic causes and drivers.

Drug shortages are an urgent public health crisis. Recent shortages have had a negative impact on the delivery and safety of appropriate health care to patients. Long-term shortages have been persistent and critical shortages of basic products such as saline are driving poor patient health outcomes, increasing the potential for medication errors, re-directing scarce administrative and clinical staff time and resources to the identification of alternative treatment options, or delaying patient treatment (such as surgeries). Several commonly used products required for patient care are in shortage, including sterile infusion solutions and injectable products that are off-patent and have few suppliers.^{1,2}

To address the drug shortage issue, AMA supports policy, legislation, and/or regulation that:

- Encourages stakeholders in the drug supply chain to increase **collaboration**.
- **Increases transparency** along the pharmaceutical supply chain.
- Establishes plans for **continuity of supply** of vital medications, including the establishment of resiliency and redundancy in manufacturing capability.
- Reduces or removes **regulatory hurdles** and barriers while enhancing flexibilities.
- **Incentivizes investment** in expanded manufacturing production capacity for vital products.

¹ U.S. Government Accountability Office (GAO), Drug Shortages: Certain Factors Are Strongly Associated with This Persistent Public Health Challenge, July 2016.

² Marc-Aminah M. For Elk. Saline Shortages—Many Causes, No Simple Solution. *New England Journal of Medicine*. 2018; 378:1472-1474.

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Collaboration

The AMA applauds the FDA's efforts thus far in engaging with a broad range of stakeholders in public meetings and listening sessions and remains committed to participating and assisting. The AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply.³ We urge stakeholders from the entirety of the drug supply chain and the FDA to work in a collaborative fashion to implement these recommendations.

Increase Transparency

The AMA strongly urges the FDA to require manufacturers to provide greater transparency regarding the drug manufacturing process from start to finish. Knowledge of the entire supply chain, including raw material suppliers, active pharmaceutical ingredient manufacturers and suppliers, distributors and distribution sites, as well as production locations of drugs, can provide the necessary metrics for much-needed quality analysis and information regarding supply chain disruptions that contribute to medical product shortages and their causes. More information about the manufacturing process can inform the causes and anticipated duration of drug shortages and assist in shortage mitigation.

Continuity of Drug Supply

The AMA strongly supports conferring the FDA with enforcement authorities to ensure that drug manufacturers establish a plan for continuity of supply of vital medications and vaccines to avoid production shortages whenever possible. The continuity of supply plan should include the establishment of the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.

The AMA strongly supports the designation of drug shortages as a national security priority and the inclusion of vital drug production sites in the critical infrastructure plan. Several manufacturers were impacted by cyber events over the past year and product shortages were worsened by the recent hurricanes impacting Puerto Rico which demonstrate the need to evaluate risk and hazard and disaster response for drug and medical product manufacturing. The AMA urges the application of critical infrastructure policies to the drug shortage challenges clinicians, their patients, and families face each day.

Reduction in Regulatory Burden

The AMA strongly supports the FDA's effort to provide increased flexibilities and engagement when manufacturers have notified the Agency of a potential or actual drug shortage. The AMA continues to specifically support expedited facility inspections and the review of manufacturing changes, drug applications, and supplements that would assist manufacturers in mitigating or preventing a drug shortage. We urge the FDA to consider whether innovative portals, technologies, or collaborations involving big data and augmented intelligence systems (also referred to as artificial intelligence) could be

³ ASHP Drug Shortages Roundtable Report, November 2018 <https://www.ashp.org/drug-shortages/shortage-resources/roundtable-report>

deployed by the FDA to forecast potential shortages and root causes including, but not limited, to regulatory policies.

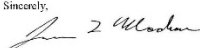
Federal Policies, Market Forces, Investment Incentives

The AMA strongly supports the development of a comprehensive report on the root causes that also analyzes current manufacturing capacity, the number of manufacturers, mergers and consolidations, economic factors including federal reimbursement practices, as well as controlling practices by market participants on competition, access to drugs, and pricing. The AMA also urges careful consideration of federal health care program payment rates for drugs that are vulnerable to shortage. The Government Accountability Office identified low profit margins for drugs in shortage as a relevant contributing factor to persistent shortages. Carefully targeted policies to address potential underinvestment in vital products subject to intractable shortages should be evaluated.

The AMA strongly supports collaboration between the Federal Trade Commission (FTC) and the FDA during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers. FTC consultation with the FDA can aid in determining the public health implications of mergers and acquisitions, including the potential impact on drug shortages. Related to the foregoing, the AMA has expressed support for expanded resources and capacity at the FTC to more fully assess and evaluate the impact of mergers and consolidations on competition as well as consumer access as part of the FTC's charge to advance consumer protection. Without oversight and intervention, drug shortages will exist into the foreseeable future if further consolidations occur reducing production capacity.

Our physician members and their patients are negatively impacted by the persistent and ongoing shortages of necessary and often basic medical products. We look forward to working closely with you and other federal agencies to take rapid, direct action where opportunity exists to permanently resolve or mitigate drug shortages. If you have questions, please contact Shannon Curtis, Assistant Director, Division of Federal Affairs at shannon.curtis@ama-assn.org or 202-789-8510.

Sincerely,



James L. Madara, MD

3. LOW NICOTINE PRODUCT STANDARD (RESOLUTION 431-A-18)

Reference committee hearing: see report of Reference Committee D.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 431-A-18
REMAINDER OF REPORT FILED**
See Policies H-495.972 and H-495.988

Resolution 431-A-18, introduced by the American Thoracic Society and referred by the House of Delegates asks:

That our American Medical Association (AMA) direct the Council on Science and Public Health to develop a report on the individual health and public health implications of a low nicotine standard for cigarettes. Such a report should consider and make recommendations on scientific criteria for selection of a nicotine standard that is non-addictive, regulatory strategies to ensure compliance with an established standard, how a low nicotine standard should work with other nicotine products in a well-regulated nicotine market.

METHODS

English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from January 2018 to January 2019 using the search terms “nicotine standard,” “nicotine content,” and “very low nicotine content cigarette.”

BACKGROUND

At the 2018 Annual Meeting of the House of Delegates, the Council on Science and Public Health (CSAPH) presented a report on “Tobacco Harm Reduction: A Comprehensive Nicotine Policy to Reduce Death and Disease Caused by Smoking.” That report outlined the Food and Drug Administration’s (FDA) plan to reduce the devastating toll of tobacco use and noted that the plan involves two primary parts: (1) reducing the addictiveness of combustible cigarettes and (2) recognizing and clarifying the role that potentially less harmful tobacco products could play in improving public health. The FDA also has acknowledged the need for medicinal nicotine and other therapeutic products to play a greater role in helping smokers to quit and remain nonsmokers.

On July 16, 2018, the AMA along with 39 other medical and public health organizations submitted comments to the Food and Drug Administration (FDA) on Docket No. FDA-2017-N-6189, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes (See Appendix).¹ These comprehensive comments on the FDA’s Advance Notice of Proposed Rule Making (ANPRM) addressed the following issues:

- I. Public Health Impact of Reducing Nicotine in Combustible Tobacco Products
 - A. Reducing the Nicotine Content of Cigarettes Will Help Smokers Quit
 - B. Reducing the Nicotine Content of Combustibles Will Prevent Kids from Becoming Addicted Smokers
 - C. Vulnerable Populations Will Benefit from a Nicotine Reduction Policy
- II. A Nicotine Content Standard Should Apply to Other Combustible Tobacco Products
 - A. The Tobacco Industry Manipulates Loopholes in Product Regulation
 - B. Cigars Are a Harmful and Addictive Substitute for Cigarettes
 - C. Hookah (Waterpipe) Tobacco is Harmful and Addictive
 - D. The rule should prohibit other changes in cigarettes that might counteract the effect of the reduction in nicotine.
- III. Implementation Considerations
 - A. Maximum Nicotine Level
 - B. An Immediate Nicotine Content Reduction Will Have a Larger Public Health Impact than a Gradual Reduction
 - C. Reducing the Nicotine Content of Combustibles Will Not Lead to Compensation
 - D. FDA Must Counter Misperceptions about the Harms of Reduced Nicotine Products

IV. Technical Achievability

- A. Reducing Nicotine in Cigarettes is Technologically Feasible
- B. FDA Should Make the Effective Date of the Rule as Early as Possible.
- C. Manufacturers, Distributors, and Retailers Should Not Be Allowed to Sell Off Existing Nonconforming Inventories.
- D. FDA Should Require a Standard Method of Product Testing to Analyze Nicotine Levels.

V. Possible Countervailing Effects

- A. The Product Standard Should Prohibit the Sale or Distribution of Liquid Nicotine or Any Other Tobacco Product Designed to Supplement the Nicotine Content of Combusted Tobacco Products.
- B. Illicit Trade

VI. Other Considerations

- A. The Potential Consumer Surplus or Utility Loss from the Removal of Nicotine from Combusted Tobacco Products is Minimal in Light of the Availability of Other Sources of Nicotine and the Continued Availability of Tobacco Products.
- B. FDA Should Consider Externalities, Such as the Reduction in Secondhand Smoke, in Evaluating the Consequences of the Rule
- C. Post-market Surveillance is Critical

The AMA also submitted individual comments (see Appendix) calling on the FDA to:

create a non-addictive nicotine level standard for all tobacco products, not just cigarettes. This includes smokeless tobacco, electronic nicotine delivery systems (ENDS), 'heat not burn products,' and any other tobacco products containing nicotine for recreational use. If FDA reduces nicotine content in combustible tobacco products without already having a regulatory strategy in place that appropriately addresses ENDS, it will miss a critical opportunity to reduce overall nicotine addiction and use of tobacco products. Comprehensive and specific regulations are necessary to prevent new products that may circumvent the nicotine level requirement.

DISCUSSION

Several studies have been released on the issue of low nicotine cigarette product standards since the AMA submitted comments to the FDA regarding a tobacco product standard for nicotine. These studies have largely been consistent with the AMA's comments or have addressed gaps where information was not previously available. One study found that when nondaily smokers switch to very low nicotine content cigarettes, they reduced their cigarette consumption by 51 percent, though they did not necessarily stop smoking.² A study looking at whether smoking intensity increased when intermittent smokers switched to very low nicotine content cigarettes found that smoking intensity decreased.³ Another study examined the effects of immediate vs. gradual reduction in nicotine content to very low levels and as compared with usual nicotine level cigarettes on biomarkers of toxicant exposure. Among smokers, immediate reduction of nicotine in cigarettes (to 0.4 mg of nicotine per gram of tobacco) led to significantly greater decreases in biomarkers of smoke exposure across time compared with gradual reduction (from 15.5 mg to 0.4 mg of nicotine per gram of tobacco cigarettes with 5 monthly dose changes) or a control group (maintenance on 15.5 mg of nicotine per gram of tobacco cigarettes), with no significant differences between gradual reduction and control.⁴

A search on clinicaltrials.gov indicates that there are a number of clinical trials underway that will provide additional information on very low nicotine content cigarettes and nicotine product standards.

CURRENT AMA POLICY

Existing AMA policy acknowledges that all tobacco products are harmful to health, and that there is no such thing as a safe cigarette. Policy also recognizes that complete cessation of the use of tobacco and nicotine-related products is the goal and supports the use of FDA-approved tools for smoking cessation. The AMA supports the FDA's regulatory authority over tobacco products and encourages the FDA and other appropriate agencies to conduct or fund research on how tobacco products might be modified to facilitate cessation of use, including elimination of nicotine and elimination of additives (e.g., ammonia) that enhance addictiveness.

RECOMMENDATION

The Council on Science and Public Health recommends that the following be adopted in lieu of Resolution 431-A-18 and the remainder of the report be filed:

1. That AMA Policy H-495.988, “FDA Regulation of Tobacco Products” be amended by addition to read as follows:

1. Our AMA: (A) acknowledges that all tobacco products (including but not limited to, cigarettes, smokeless tobacco, chewing tobacco, and hookah/water pipe tobacco) are harmful to health, and that there is no such thing as a safe cigarette; (B) recognizes that currently available evidence from short-term studies points to electronic cigarettes as containing fewer toxicants than combustible cigarettes, but the use of electronic cigarettes is not harmless and increases youth risk of using combustible tobacco cigarettes; (C) encourages long-term studies of vaping (the use of electronic nicotine delivery systems) and recognizes that complete cessation of the use of tobacco and nicotine-related products is the goal; (D) asserts that tobacco is a raw form of the drug nicotine and that tobacco products are delivery devices for an addictive substance; (E) reaffirms its position that the Food and Drug Administration (FDA) does, and should continue to have, authority to regulate tobacco products, including their manufacture, sale, distribution, and marketing; (F) strongly supports the substance of the August 1996 FDA regulations intended to reduce use of tobacco by children and adolescents as sound public health policy and opposes any federal legislative proposal that would weaken the proposed FDA regulations; (G) urges Congress to pass legislation to phase in the production of reduced nicotine-content tobacco products, and to authorize the FDA have broad-based powers to regulate tobacco products; (H) encourages the FDA and other appropriate agencies to conduct or fund research on how tobacco products might be modified to facilitate cessation of use, including elimination of nicotine and elimination of additives (e.g., ammonia) that enhance addictiveness; and (I) strongly opposes legislation which would undermine the FDA's authority to regulate tobacco products and encourages state medical associations to contact their state delegations to oppose legislation which would undermine the FDA's authority to regulate tobacco products.

2. Our AMA: (A) supports the US Food and Drug Administration (FDA) as it takes an important first step in establishing basic regulations of all tobacco products; (B) strongly opposes any FDA rule that exempts any tobacco or nicotine-containing product, including all cigars, from FDA regulation; and (C) will join with physician and public health organizations in submitting comments on FDA proposed rule to regulate all tobacco products.

3. Our AMA: (A) will continue to monitor the FDA's progress towards establishing a low nicotine product standard for tobacco products and will submit comments on the proposed rule that are in line with the current scientific evidence and (B) recognizes that rigorous and comprehensive post-market surveillance and product testing to monitor for unintended tobacco use patterns will be critical to the success of a nicotine reduction policy.

2. That American Medical Association Policy H-495.972, “Electronic Cigarettes, Vaping, and Health” be reaffirmed.

REFERENCES

1. Food and Drug Administration, Tobacco Product Standard for Nicotine Level of Combusted Cigarettes. 83 FR 11818, pgs. 11818-11843. Available at: <https://www.federalregister.gov/documents/2018/03/16/2018-05345/tobacco-product-standard-for-nicotine-level-of-combusted-cigarettes>. Accessed March 1, 2019
2. Shiffman S, Kurland BF, Scholl SM, Mao JM. Nondaily Smokers' Changes in Cigarette Consumption With Very Low-Nicotine-Content Cigarettes: A Randomized Double-blind Clinical Trial. *JAMA Psychiatry*. 2018;75(10):995–1002.
3. Shiffman S, Mao JM, Kurland BF, Scholl SM. Do non-daily smokers compensate for reduced cigarette consumption when smoking very-low-nicotine-content cigarettes? *Psychopharmacology* (Berl). 2018; 235(12):3435-3441.
4. Hatsukami, D. K., Luo, X., Jensen, J. A., Al'Absi, M., Allen, S. S., Carmella, S. G., Donny, E. C. Effect of immediate vs gradual reduction in nicotine content of cigarettes on biomarkers of smoke exposure a randomized clinical trial. *JAMA - Journal of the American Medical Association*. 2018; 320(9): 880-891.

[Editor's note: the appendices referenced in this report are available from the Council on Science and Public Health.]

4. VECTOR-BORNE DISEASES (RESOLUTION 430-A-18, FIRST AND SECOND RESOLVES)

Reference committee hearing: see report of Reference Committee D.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF THE FIRST AND SECOND RESOLVES OF RESOLUTION 430-A-18
REMAINDER OF REPORT FILED**

See Policies H-135.938, H-440.820 and D-440.940

The first and second resolves of Resolution 430-A-18, introduced by the American Academy of Dermatology along with 24 state and national medical specialty societies, and referred by the House of Delegates asks:

That our American Medical Association (AMA) study the emerging epidemic of vector-borne diseases including an analysis of currently available testing and treatment standards and their effectiveness, and issue a white paper on vector-borne diseases (VBD) for the purpose of increasing awareness of the epidemic of vector-borne diseases.

METHODS

English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from January 2014 to January 2019 using the search terms “vector-borne disease,” “tick-borne disease,” “mosquito-borne disease,” “Lyme disease,” “post treatment Lyme disease,” “chronic Lyme disease,” “West Nile virus,” and “Zika virus.” Additional articles were identified by manual review of the reference lists of pertinent publications. Websites managed by federal, state, and local agencies and applicable national public health, entomology, and mosquito control organizations also were reviewed for relevant information.

CURRENT AMA POLICY

Existing AMA policy on VBD urges the AMA to support educating the medical community on the potential adverse public health effects, including VBDs, of global climate change. Policy also calls on the AMA to advocate for local, state and national research, education, reporting, and tracking on VBDs. Our policy on zoonotic diseases asks the AMA to collaborate with the American Veterinary Medical Association and other stakeholders to take the lead in establishing a robust, coordinated, and effective global surveillance system of zoonotic diseases in humans and syndromic outbreaks in animals. In terms of policy on specific VBDs, existing policy addresses Zika virus by calling for funding and the development of strategies to limit the spread and impact of the virus as well as approaches to minimize the transmission to potentially pregnant women.

BACKGROUND

Vectors are blood-feeding insects and ticks capable of transmitting pathogens between hosts. Wide varieties of pathogens have evolved to exploit vector transmission, including some viruses, bacteria, rickettsia, protozoa, and helminths.¹ Mosquitos, ticks, and fleas are the most common vectors in the United States. Diseases from mosquito and tick bites occur in every U.S. state and territory.² The growing incidence of Lyme disease and recent outbreaks of Zika virus and chikungunya points to the need for comprehensive VBD programs and for increased awareness of these diseases by clinicians and patients. Climate change creates additional concern about the spread of VBDs as changing temperatures may expand the geographic range of disease-carrying insects.

EPIDEMIOLOGY

VBDs are a major cause of death and illness worldwide. Every year, VBDs such as malaria, dengue, and yellow fever, account for more than 700,000 deaths globally.³ The burden of these diseases is highest in tropical and subtropical areas and they disproportionately affect poor populations.³ In the United States, 16 VBDs are reportable to state and territorial health departments and the National Notifiable Disease Surveillance System. The most common VBDs in the United States are Lyme disease, Rocky Mountain spotted fever, West Nile virus (WNV), dengue, and Zika virus disease.² Malaria and yellow fever are no longer transmitted in the United States, but are monitored because they have potential to re-emerge. As a group, VBDs in the United States are notable for their wide distribution and resistance to control.¹ Yellow fever is the only nationally notifiable VBD for which there is an FDA-approved vaccine available.²

In the United States, nearly 650,000 cases of VBD were reported from 2004–2016.¹ Reported cases of tick-borne disease (TBD) doubled in the 13-year analysis period.¹ TBDs account for more than 75 percent of VBDs reports throughout the continental United States and Lyme disease accounts for the majority (82 percent) of cumulative reported TBD.¹ In addition to Lyme disease, other common illnesses caused by ticks are Rocky Mountain spotted fever, babesiosis, ehrlichiosis, anaplasmosis, tularemia, Colorado tick fever, tick-borne relapsing fever, and Powassan disease. While TBDs are prevalent throughout the country, they are predominately found along the northeastern coast, in the upper Midwest, and along the Pacific coast.

WNV was the most commonly transmitted mosquito-borne disease (MBD) in the continental United States from 2004–2016, with the largest outbreak occurring in 2012.¹ Epidemics of dengue, chikungunya, and Zika viruses were mostly confined to the U.S. territories. Travelers infected in the territories and Latin America accounted for more than 90 percent of the dengue, chikungunya, and Zika virus cases identified in the continental United States.¹ Limited local transmission of dengue occurred in Florida, Hawaii, and Texas, and of chikungunya and Zika viruses in Texas and Florida.¹ Malaria was diagnosed in approximately 1,500 travelers yearly, but no local transmission was documented from 2004–2016.¹

Given the broad range of VBDs, CSAPH decided to focus the scope of this report broadly on the prevention of VBDs, followed by specific discussions on the most prevalent TBDs and MBDs – Lyme disease and WNV, respectively.

PREVENTION OF VBDs

Vector Control Programs

Vector control programs vary by jurisdiction. These responsibilities may fall to the local health department, mosquito control district, or a variety of other local agencies (public works, streets and sanitation, parks and recreation, or other environmental health services).⁴ The result is differing capabilities across the country. The Centers for Disease Control and Prevention (CDC) has outlined core competencies for vector control programs. The competencies include: (1) routine mosquito surveillance through standardized trapping and species identification; (2) treatment decisions using surveillance data; (3) larviciding, adulticiding, or both; (4) routine vector control activities (i.e., chemical, biological, source reduction, or environmental management); and (5) pesticide resistance testing. There are five supplemental competencies, these include (1) licensed pesticide application; (2) vector control other than chemical control (i.e., biological, source reduction, or water management); (3) community outreach and education campaigns regarding mosquito-borne diseases, how they spread, and how to prevent infection; (4) regular communication with local health departments regarding surveillance and epidemiology; and (5) outreach (i.e., communication and/or cooperation).

A survey of vector control organizations in the United States (n=1,083) found that based on the CDC competencies, 34 percent of mosquito control districts perform all core competencies versus 6 percent and 7 percent of local health departments and other organizations, respectively.⁴ Of the competencies that vector control programs ranked as “needs improvement,” nearly all of them (98 percent) lacked the capability or capacity to perform pesticide resistance testing.⁴ More than half also lack the ability to perform routine surveillance and species identification.⁴

Another approach to vector control that is being considered to prevent VBDs is the use of novel technologies. One example is the use of genetically engineered mosquitos to prevent the spread of Zika virus. Specifically, the male *Aedes aegypti* mosquitos are genetically engineered to express a gene that encodes a conditional or repressible lethality trait and a red fluorescent marker protein to aid in the identification of these mosquitos.²⁶ If a female *Aedes* mosquito mates with a sterile male then it will have no offspring, reducing the next generation’s population.²⁶ Repeated release of insects can reduce the insect population to very low levels. The Environmental Protection Agency (EPA) has been considering a pilot to determine the efficacy of these genetically engineered mosquitos in the Florida Keys.

Personal Protection from Vectors

For mosquitos, personal protection from vectors involves using an EPA-registered insect repellent with one of the following active ingredients: DEET, Picaridin, IR3535, oil of lemon eucalyptus or para-methane-diol, or 2-undecanone.⁵ Individuals should also treat items such as boots, pants, socks, and tents with permethrin or purchase permethrin-treated clothing and gear.⁵ Homes should also be mosquito-proofed by using screens on windows and doors and repairing holes in screens to keep mosquitos outside.⁵ It is also recommended to use air conditioning when available and to eliminate standing water outside your home to keep mosquitos from laying eggs.⁵ It is important to

remember that vector-borne diseases affect the poor disproportionately. Overall, changes in living conditions in the United States have resulted in decreased local transmission of MBD such as yellow fever, malaria, and dengue.²²

For ticks, the use of EPA-registered insect repellents and permethrin treating clothing and gear is also recommended. Individuals are encouraged to avoid contact with ticks by avoiding wooded and brushy areas with high grass and leaf litter, and walk in the center of trails.⁶ Once indoors, individuals should check their clothing and body for ticks after being outdoors. Showering within two hours of coming indoors has been shown to reduce the risk of Lyme disease as it may help wash off unattached ticks.⁶ If a tick is attached to the skin the key is to remove it as soon as possible by using fine-tipped tweezers to grasp the tick as close to the skin's surface as possible and pull upward.⁷ Testing of ticks for evidence of infection is not recommended.⁷

DISCUSSION

Once an individual has been bit by an infected vector and/or suspects they may have been exposed to a VBDs, health care professionals may be consulted for diagnosis and treatment. The CDC has developed a reference manual for health care providers on tick-borne diseases in the United States that provides an overview of ticks and the infections they transmit.⁶ The manual also provides information on incubation periods, signs and symptoms, diagnosis, and treatment.⁶ A similar manual for MBDs and other VBDs does not currently exist.

Lyme Disease

Lyme disease, the leading VBD in the United States, is caused by *Borrelia burgdorferi*, which is transmitted by the bite of the tick species *Ixodes scapularis* and *Ixodes pacificus*. In 2017, a total of 42,743 confirmed and probable cases of Lyme disease were reported to CDC, nearly 9 percent more than the previous year.⁸ The geographic distribution of Lyme disease appears to be expanding. The number of counties with an incidence of ≥ 10 confirmed cases per 100,000 persons increased from 324 in 2008 to 454 in 2017.⁸

Signs and Symptoms. The majority (70 to 80 percent) of patients with Lyme disease develop the characteristic skin lesion, erythema migrans (EM).¹² The rash begins at the site of the tick bite and expands. It sometimes has a target or "bull's-eye" appearance. Other early signs include flu like symptoms – fever, chills, headache, fatigue, muscle and joint aches, and swollen lymph nodes.⁹ Longer-term symptoms include severe headaches and neck stiffness, additional EM rashes, arthritis, facial palsy, Lyme carditis, nerve pain, and inflammation of the brain and spinal cord.⁹ Recurrent large-joint arthritis signals late disseminated disease (more than six months post bite).¹⁰ Late neurologic Lyme disease signaled by peripheral neuropathy, encephalopathy, or encephalomyelitis is uncommon in the United States.¹⁰

Diagnosis. There are 3 stages of *B. burgdorferi* infection: early localized, early disseminated, and late disseminated.¹⁰ Patients with an EM lesion and epidemiologic risk can receive a Lyme diagnosis without laboratory testing. However, for all other patients, laboratory testing is necessary to confirm the diagnosis.¹⁰

Serological assays that detect antibodies against *B. burgdorferi* are the only lab test cleared by FDA and recommended by CDC for diagnosis of Lyme disease. A two-step process is used to diagnose Lyme disease (See Figure 1.) The first required test is the Enzyme Immunoassay (EIA) or Immunofluorescence Assay (IFA). If this test yields negative results, the provider should consider an alternative diagnosis; or in cases where the patient has had symptoms for less than or equal to 30 days, the provider may treat the patient and follow up with a convalescent serum. If the first test yields positive or equivocal results, two options are available: (1) If the patient has had symptoms for less than or equal to 30 days, an IgM Western Blot is performed; and (2) if the patient has had symptoms for more than 30 days, the IgG Western Blot is performed. The IgM should not be used if the patient has been sick for more than 30 days. The sensitivity of 2-tiered testing is low (30–40 percent) during early infection while the antibody response is developing.¹⁰ For disseminated Lyme disease, sensitivity is 70–100 percent. Specificity is high (>95 percent) during all stages of disease.¹⁰

Since serological tests measure a person's past or present immune response to infection, they can be negative during first several days to weeks of infection. This results in patients not being diagnosed with appropriate diseases or receiving proper treatment. Serologic tests also cannot distinguish active infection, past infection, or reinfection. In cases of reinfection, it may be helpful to conduct acute-phase and convalescent-phase serologic analysis to detect an increase in EIA titer or an increase in the number of antibody bands that might indicate active infection.¹⁰ When

determining whether to test for Lyme disease, clinicians must consider a patient's pretest probability as false-positive results can occur when tests are performed for patients with low pretest probability.¹⁰

There have been recent proposals to change the recommended 2-tier algorithm for serologic testing for Lyme disease from the current standard to one in which a second-tier EIA would be used instead of a Western blot.^{10,11} This approach would make the tests easier to perform, results would be available sooner, costs would be reduced, and it would eliminate the subjective element inherent in interpretation of Western blots.¹¹ Further research is needed.^{10,11}

Treatment. Patients treated during the early stages of Lyme disease typically recover rapidly and have good outcomes. Treatment guidelines developed by the Infectious Diseases Society of America recommend that early localized disease be treated with oral antibiotics.²³ Doxycycline 100 mg orally twice daily for 10–21 days, or cefuroxime axetil 500 mg orally twice daily or amoxicillin 500 mg orally 3 times daily for 14–21 days, has been shown to be effective in resolving early Lyme disease and in preventing progression.²³ People with certain neurological or cardiac forms of illness may require intravenous treatment with antibiotics such as ceftriaxone or penicillin.²³

While most patients diagnosed with early acute Lyme disease who are treated with appropriate courses of antimicrobial therapy become symptom free, 10–20 percent of patients continue to experience symptoms that can persist for six months or longer. Post-treatment Lyme Disease (PTLD) or “chronic Lyme disease” commonly refers to the continuation of such symptoms as fatigue, myalgia, arthralgia, memory loss, and headache after antibiotic therapy for Lyme disease. Whether chronic disease is a legitimate clinical entity has become highly controversial.^{12–15,23,30} The mechanism behind this persistence in some patients is unknown, but has been suggested to be due to preexisting damage from the inflammatory response to infection, from persistent low-level infection, or to an autoimmune response.¹³ Trials examining the effect of repeated antibiotic treatment in PTLS have shown no significant sustained benefit.^{13,23} The Infectious Diseases Society of America is currently in the process of updating their guidelines on Lyme disease, with a project publication date of Winter 2020.

Costs. A comprehensive understanding of the full economic and societal costs of Lyme disease remains unknown. The total direct medical costs attributable to Lyme disease and PTLD are estimated to be somewhere between \$712 million - \$1.3 billion each year in the United States.²⁸

Vaccine. LYMERix™, a noninfectious recombinant vaccine for Lyme disease, was available in the United States from 1998-2002.²¹ The Food and Drug Administration approved vaccine, which reduced new infections in vaccinated adults by nearly 80 percent, was voluntarily withdrawn from the market because of media coverage, fears of vaccine side-effects, and declining sales.²⁷

West Nile Virus

WNV is the leading cause of mosquito-borne disease in the continental United States. In 2018, 49 states and the District of Columbia reported WNV infections in people, birds, or mosquitoes. 2,544 cases of WNV in people were reported to CDC last year.²⁵ Of these, 1,594 (63 percent) were classified as neuroinvasive disease and 950 (37 percent) were classified as non-neuroinvasive disease.²⁵ In 2018, 137 deaths were reported.²⁵

Signs and Symptoms. Most people infected with WNV do not develop any symptoms.¹⁶ Approximately 1 in 5 people will develop a fever as well as headache, body aches, joint pains, vomiting, diarrhea, or rash.¹⁶ About 1 in 150 people who are infected develop a severe illness affecting the central nervous system such as encephalitis or meningitis.¹⁶ Symptoms of severe illness include high fever, headache, neck stiffness, stupor, disorientation, coma, tremors, convulsions, muscle weakness, vision loss, numbness and paralysis.¹⁶

Diagnosis. Diagnosis of WNV is generally accomplished through laboratory testing of serum or cerebrospinal fluid (CSF) to detect WNV-specific IgM antibodies, which are usually detectable three to eight days after onset of illness and persist for 30 to 90 days.¹⁶ Positive results obtained with these assays should be confirmed by neutralizing antibody testing of acute- and convalescent-phase serum specimens at a state public health laboratory or CDC. WNV IgG antibodies generally are detected shortly after IgM antibodies and persist for many years. Therefore, the presence of IgG antibodies alone is only evidence of previous infection.¹⁶

Viral cultures and tests to detect viral RNA (i.e., reverse transcriptase-polymerase chain reaction) can be performed on serum, CSF, and tissue specimens that are collected early in the course of illness and, if results are positive, can

confirm an infection. Immunohistochemistry can detect WNV antigen in formalin-fixed tissue.¹⁶ Negative results of these tests do not rule out WNV infection.¹⁶

Treatment. There is no specific treatment for WNV disease. Patients with severe meningeal symptoms may require pain control for headaches and antiemetic therapy and rehydration for associated nausea and vomiting.¹⁶ Patients with encephalitis require close monitoring for the development of elevated intracranial pressure and seizures.¹⁶ Patients with encephalitis or poliomyelitis should be monitored for inability to protect their airway.¹⁶ Acute neuromuscular respiratory failure may develop rapidly and prolonged ventilatory support may be required.¹⁶

Costs. Data suggests the total cumulative costs of reported WNV hospitalized case-patients during 1999–2012 were \$778 million, which is an average of approximately \$56 million per year.²⁹

Vaccines. There are no WNV vaccines licensed for use in humans.

EMERGING AND RE-EMERGING VBDs

Since 2004, the United States has seen an increasing number of new or re-emerging vector-borne pathogens.^{1,20} This includes previously unknown tick-borne RNA viruses, a tick-borne relapsing fever agent, and two tick-borne spotted fever species as well as the introduction of mosquito viruses, chikungunya and Zika, introduced in Puerto Rico in 2014 and 2015, respectively.¹

Zika virus disease

Zika virus is a Flavivirus, which is transmitted to humans primarily through the bite of an infected *Aedes* species mosquito (*Ae. aegypti* and *Ae. albopictus*).¹⁷ In 2015 and 2016, outbreaks of Zika virus occurred in the Americas, resulting in travel-associated cases in the United States, widespread transmission in the U.S. territories, and limited local transmission in Florida and Texas.¹⁸ Zika virus infection during pregnancy has been demonstrated to cause birth defects such as microcephaly and other severe brain defects.¹⁸ From January 15 through December 27, 2016, a total of 1,297 pregnancies with possible Zika virus infection were reported to the U.S. Zika Pregnancy Registry.²⁴ Birth defects were reported for 51 (5 percent) of the 972 completed pregnancies with laboratory evidence of possible recent Zika virus infection.²⁴ Zika is the only arbovirus known to be transmitted sexually.

Longhorned Tick (Haemaphysalis longicornis)

Haemaphysalis longicornis is indigenous to eastern Asia and is an important vector of human and animal disease agents, including Rickettsia, Borrelia, Ehrlichia, Anaplasma, Theileria, and several important viral agents such as Heartland and Powassan viruses.¹⁹ *Haemaphysalis longicornis* was discovered on a sheep in New Jersey in August 2017. From August 2017 through September 2018, vector and animal surveillance efforts resulted in 53 reports of *Haemaphysalis longicornis* in the United States, including 38 from animal species (23 from domestic animals, 13 from wildlife, and two from humans), and 15 from environmental sampling of grass or other vegetation.¹⁹ Most of these reports have come from the eastern portion of United States.¹⁹ No cases of illness in humans or other species have been reported to date.¹⁹

CONCLUSION

VBDs are a growing health threat in the United States and one that climate change is expected to exacerbate. The most common VBDs in the United States are Lyme disease, Rocky Mountain spotted fever, WNV, dengue, and Zika virus disease. From a public health perspective, to effectively reduce transmission and respond to VBD outbreaks, improvements in surveillance, reporting, and adequate vector control will be necessary, but as a nation we currently have limited capacity to respond to vector-borne diseases. With approximately 80 percent of our nation's vector control organizations lacking critical prevention and control capacities, sustained investment in improving these capabilities is needed as are investments in our public health infrastructure and workforce.

For health professionals to adequately care for patients infected with VBDs, clinical research is needed to improve their diagnosis and treatment. Educating health professionals and the public about existing and emerging VBDs will be critical to addressing both prevention and treatment efforts. Lyme disease should be an area of focus in these efforts since it is the most common VBD in the United States. Furthermore, with there being only one nationally notifiable

VBD with an FDA approved vaccine available, vaccine development for VBDs should be prioritized. To accomplish these goals, additional and sustained funding for VBDs will be necessary.

RECOMMENDATIONS

The Council recommends that the following statements be adopted in lieu of Resolution 403-A-18, and the remainder of the report be filed.

1. That Policy H-440.820, “Vector-Borne Diseases,” be amended by addition and deletion to read as follows:

H-440.820, Vector-Borne Diseases

Due to the increasing threat and limited capacity to respond to vector-borne diseases, Our our AMA supports and will advocate for local, state and national research, education, reporting and tracking on vector borne diseases.

- (1) Improved surveillance for vector-borne diseases to better understand the geographic distribution of infectious vectors and where people are at risk;
 - (2) The development and funding of comprehensive and coordinated vector-borne disease prevention and control programs at the federal, state and local level;
 - (3) Investments that strengthen our nation’s public health infrastructure and the public health workforce;
 - (4) Education and training for health care professionals and the public about the risk of vector-borne diseases and prevention efforts as well as the dissemination of available information;
 - (5) Research to develop new vaccines, diagnostics, and treatments for existing and emerging vector-borne diseases, including Lyme disease;
 - (6) Research to identify novel methods for controlling vectors and vector-borne diseases; and
 - (7) Increased and sustained funding to address the growing burden of vector-borne diseases in the United States.
2. That Policy H-135.938, “Global Climate Change and Human Health” and Policy, D-440.940, “Global Tracking System of Zoonotic Diseases,” be reaffirmed.

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Figure 1.

