

REPORTS OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

The following reports were presented by Robert A. Gilchick, MD, MPH, Chair.

1. CSAPH SUNSET REVIEW OF 2008 HOUSE OF DELEGATES POLICIES

Reference committee hearing: see report of Reference Committee D.

HOUSE ACTION: RECOMMENDATIONS ADOPTED 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 2008 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 that are 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 2008 House Policies and Directives

Policy Number	Title	Recommended Action and Rationale
D-15.999	Options for Improving Motorcycle Safety	Retain in part. Part 1 was accomplished by NHTSA's publishing in November 2006 of national motorcycle guidelines. Retain part 2 and amend to H-policy. Our AMA: (1) encourages the National Highway Traffic Safety Administration to work with medical and public health organizations, national motorcycle rider organizations, state motor vehicle licensing agencies, law enforcement officials, and the motorcycle industry to develop a comprehensive national motorcycle safety plan that addresses rider education, training, and licensing; use of motorcycle helmets and other protective gear; public awareness of motorcycles; alcohol use among motorcyclists and other motor vehicle drivers; measures to increase the visibility of motorcyclists and motorcycles to other drivers; engineering and design of motorcycles and highway environments; and research to determine the effectiveness of current and proposed safety measures; and (2) encourages physicians to (a) be aware of motorcycle risks and safety measures and (b) counsel their patients who ride motorcycles to wear appropriate protective gear and helmets that meet federal safety standards, receive appropriate training in the safe operation of their motorcycle, comply with state licensing laws, and avoid riding a motorcycle while under the influence of alcohol and other drugs.
D-20.989	HIV and Public Health Prevention Services	Rescind. Accomplished.
D-20.990	Global HIV/AIDS Prevention	Retain in part to read as follows and change to H-policy: Our AMA extends its supports of comprehensive family-life education to foreign aid programs to prevent the spread of HIV/AIDS and other sexually transmitted diseases.
D-20.998	Bloodborne Pathogen Transmission to and from Health Care Workers	Rescind. The CDC published updated recommendations for the Hepatitis B Virus-infected health care providers and students in 2012. Updated guidance on HIV in the health care setting is also available. SHEA has also developed guidelines for the management of health care workers with HBV, HCV and/or HIV.
D-55.997	Cancer and Health Care Disparities Among Minority Women	Retain in part to read as follows and change to H-policy: Our AMA: (1) encourages research and funding directed at addressing racial and ethnic disparities in minority women pertaining to cancer screening, diagnosis, and treatment; and (2) will work with the National Cancer Institute's Center to Reduce Cancer Health Disparities, the American Cancer Society, and other organizations to promote the use among minority women of educational materials that are culturally sensitive and at the appropriate literacy level.
D-60.971	Reduction of Underage Drinking	Retain. Change to H-policy.
D-60.972	Internet Marketing to Children on Health	Rescind. Online tools exist to educate children about health habits and lifestyles.
D-95.982	Drug Abuse and Relapse Reduction Through Patient Identifiers as a Chronic Disease	Retain in part to read as follows because a portion is no longer relevant and change to H-policy: Our AMA: (1) strongly urges health care providers to take an active role in acknowledging the diagnosis of that addiction is a chronic disease; and (2) will partner with organizations such as the American Society of Addiction Medicine, to explore the use of medication contracts to monitor the use of prescribed medications in patients with a known history of addiction.
D-95.984	Substance Use and Substance Use Disorders	Retain. Change to H-policy.
D-115.991	Manufacturer Labeling of Medical Supplies	Rescind. Accomplished by Unique Device Identifier regulations.
D-155.999	Energy Efficiency and Medical Practice	Retain. Still relevant.

D-165.997	Physician Education of Their Patients About Prescription Medicines	Rescind. Accomplished by support and dissemination of Guidelines for Physicians for Counseling Patients about Prescription Medications in the Ambulatory Setting.
D-170.998	Alcohol and Youth	Retain. Still relevant.
D-425.994	Early Recognition and Intervention in Chronic Kidney Disease	Rescind. Updated guidelines issued August 2012.
D-425.999	Public and Private Funding of Prevention Research	Retain in part to read as follows and change to H-policy: (1) Our AMA will seek to work in partnership with the Centers for Disease Control and Prevention, the National Institutes of Health, and other Federal Agencies, the Public Health Community (via the medicine/public health initiative) , and the managed care community to develop ensure that there is a national prevention research agenda and report back to the House of Delegates the current status of this agenda. (2) These groups work in partnership to develop a practical plan to implement recommendations which will allow such groups to support and participate more fully in prevention research.
D-470.992	Implementation of Automated External Defibrillators in High-School and College Sports Programs	Retain. Only 17 of 50 states have some type of legislation dealing with AEDs in schools, most commonly a requirement for AEDs in public grade schools or in both public grade schools and colleges.
D-490.998	Tobacco Control and Settlement	Retain. Still an important issue.
D-495.996	Opposition to Addition of Flavors to Cigarettes	Retain. Change to H-policy.
D-515.984	Health Care Costs of Violence and Abuse Across the Lifespan	Retain in part to read as follows and change to H-policy: 1. Our AMA urges Congress the National Academies of Sciences, Engineering, and Medicine to commission the Institute of Medicine continue to study and issue a report on the impact and health care costs of violence and abuse across the lifespan. 2. Our AMA: (a) encourages the National Institutes of Health, the Agency for Healthcare Research and Quality, and the Centers for Disease Control and Prevention to conduct research on the cost savings resulting from health interventions on violence and abuse; and (b) will develop and implement a strategy to advocate for increased funding for such research. 3. Our AMA encourages the appropriate federal agencies to increase funding for research on the impact and health care costs of elder mistreatment.
H-10.970	Use of Protective Eyewear by Athletes	Retain. AAP and AAO policies remain in place.
H-10.989	Better Fire Prevention in Public Buildings	Retain in part to read as follows: The AMA urges state public authorities to consider enactment of uniform fire protection codes in public buildings, for the risks such furnishings hold for the emission of toxic gases as well as intense heat, and at least in the case of new construction, the introduction of expanded sprinkler systems and fully automatic smoke detectors.
H-15.998	Driver Education in Secondary Schools	Rescind. State departments of motor vehicles have the authority to approve driver education courses that are in line with current standards and many have approved several different delivery options, which are considered acceptable.
H-20.897	Prevalence of HIV in Minority Populations	Retain. Still important.
H-20.905	HIV/AIDS Research	Retain in part to read as follows: (1) Information on the HIV Epidemic Our AMA: a) Vigorously supports the need for adequate government funding for research, both basic and clinical, in relation to HIV/AIDS epidemic. Research on HIV should be prioritized, funded, and implemented in an expeditious manner consistent with appropriate scientific rigor, and the results of research should form the basis for future programs of prevention and treatment; b) Requests the Secretary of the Department of Health and Human Services to make available information on HIV expenditures, services, programs, projects, and research of agencies under his/her jurisdiction and, to the extent possible, of all other federal agencies for purposes of

		<p>study, analysis, and comment. The compilation should be sufficiently detailed that the nature of the expenditures can be readily determined;</p> <p>c) Supports ongoing efforts of the Centers for Disease Control and Prevention to periodically monitor the incidence and prevalence of HIV infection in the U.S. population as a whole, as well as in groups of special interest such as adolescents and minorities;</p> <p>d) Encourages federal and state agencies, in cooperation with medical societies and other interested organizations, to study and report means to increase access to quality care for women and children who are HIV-infected;</p> <p>e) Encourages further research to assess the risk of HIV transmission in specific surgical techniques and how any such risk may be decreased;</p> <p>f) Supports exploring ways to increase public awareness of the benefits of animal studies in HIV/AIDS research.</p> <p>(2) Lookback Studies Our AMA encourages the cooperation of the medical community and patients in scientifically sound look back studies designed to further define the risk of HIV transmission from an infected physician to a patient and to determine if there is any scientific basis for the development of a list of exposure prone procedures. A panel of experts should be assembled to translate available look back information into a meaningful statement on the estimated true risk of transmission and the need, if any, for additional studies.</p> <p>(3) (2) Community Research Initiatives Our AMA supports the objectives of community-based research to reduce HIV disease and encourages periodic review of progress toward these objectives.</p>
H-30.940	AMA Policy Consolidation: Labeling Advertising, and Promotion of Alcoholic Beverages	Retain. Still relevant.
H-30.999	Admission of Alcoholics to General Hospitals	Rescind. Covered by "Recommendations for AMA Involvement in Alcoholism Activities," H-30.998.
H-45.980	Airborne Infections on Commercial Flights	<p>Retain in part to read as follows:</p> <p>(1) Under usual aircraft operation procedures, cabin air quality does not present a significant risk for transmission of airborne infections. (2) The AMA supports efforts of the Aerospace Medicine <u>Medical</u> Association and other groups to determine standards for cabin air quality and to educate physicians and the public about the public health risks associated with flying with airborne transmissible diseases. (3) The AMA supports the ongoing research of organizations such as the American Society of Heating, Refrigeration and Air Conditioning Engineers and the National Institute of Occupational Safety and Health to determine standards for cabin air quality.</p>
H-45.992	Airplane Safety	Retain. Still an issue.
H-50.986	Blood Donations by Donors over 65 Years of Age	Rescind. No upper limit exists on the age for blood donation.
H-50.987	Autologous Transfusions for Elective Surgery	Retain. Still relevant.
H-50.998	Definition of Blood as a Medical Service	Retain. Still relevant.
H-50.999	Blood Banks	Rescind. Strict regulatory oversight in place.
H-515.961	Elder Mistreatment	Retain. Still an issue.
H-55.979	Genetic Susceptibility Testing for Hereditary Cancers	Retain. Still relevant.
H-55.988	Uniform Cancer Staging	Retain. Still relevant.
H-60.931	Toy Safety	Rescind. Toy safety standards in place.
H-60.932	Ensuring the Best In-School Care for Children with Diabetes	Retain. Still important.
H-60.947	Guns in School Settings	Retain. Still relevant.
H-60.958	Rights of Minors to Consent for STD/HIV Prevention, Diagnosis and Treatment	Retain. Still relevant.

H-60.989	Sexually Oriented Advertising to Youth	Retain. Still relevant.
H-60.990	Child Pornography	Retain. Still an issue.
H-95.951	Role of Self-Help in Addiction Treatment	Retain in part to read as follows: The AMA: (1) recognizes that (a) patients in need of treatment for alcohol or other drug-related <u>substance use</u> disorders should be treated for these medical conditions by qualified professionals in a manner consonant with accepted practice guidelines and patient placement criteria; and (b) self-help groups are valuable resources for many patients and their families and should be utilized by physicians as adjuncts to a treatment plan; and (2) urges managed care organizations and insurers to consider self-help as a complement to, not a substitute for, treatment directed by professionals, and to refrain from using their patient's involvement in self-help activities as a basis for denying authorization for payment for professional treatment of patients and their families who need such care.
H-95.980	Increased Funding for Drug-Related Programs	Retain. Still relevant.
H-100.970	Informational Campaign on Diethylstilbesterol	Rescind. CDC program is no longer in place.
H-100.985	Need for Requirements of Ongoing Quality Assurance of the Bioavailability of Purity of Prescription Pharmaceuticals	Rescind. Appropriate regulations are in place.
H-100.987	Insufficient Testing of Pharmaceutical Agents in Children	Retain. Still relevant.
H-100.989	A Transitional Class for Drugs	Retain. Still relevant.
H-120.942	Personal Medication Supply in Times of Disaster	Retain. Still an issue.
H-125.981	Generic Medications	Retain in part to read as follows: Our AMA encourages the Food and Drug Administration to reexamine the <u>maintain</u> standards and criteria used for approving generic medications to ensure bioequivalence under various conditions and in relevant patient populations.
H-125.995	Therapeutic and Pharmaceutical Alternatives by Pharmacists	Retain in part to read as follows: The AMA opposes legislative attempts at any level of government that would permit pharmacists, when presented with a prescription for a drug product, to: (1) dispense instead a drug product that is administered by the same route and which contains the same pharmaceutical moiety and strength, but which differs in the salt or dosage form (pharmaceutical alternatives); and (2) dispense a drug product containing a different pharmaceutical moiety but which is of the same therapeutic and/or pharmacological class (therapeutic substitution). Our AMA will work with state medical associations to ensure that state pharmacy laws and medical practice acts are properly enforced so that a treating physician's prescriptions <u>directions</u> cannot be overruled or substituted without prior physician approval. If this issue is not addressed in existing laws, our AMA will develop model legislation to assist state medical associations in this endeavor.
H-130.943	Physician Identification in Emergencies	The center is no longer operational. Retain in part to read as follows: Our AMA, through the Center on Public Health Preparedness and Disaster Response , will continue to : (1) monitor the development of volunteer registration systems, such as Emergency System for Advanced Registration of Volunteer Health Professionals (ESAR-VHP), as well as volunteer organizations, such as the Medical Reserve Corps (MRC), and report back as appropriate; and (2) support the development of laws and policies such as license reciprocity and civil liability protections that encourage physicians to volunteer services during disasters.
H-130.999	Health System Security for Disasters	Rescind. Covered by part 7 of "AMA Leadership in the Medical Response to Terrorism and Other Disasters," H-130.946.
H-135.940	Toxic Disposable Consumer Products	Retain. Still relevant.
H-135.952	Manganese in Gasoline	Retain. Still relevant.

H-135.981	Medical Perspective on Nuclear Power	Rescind. Relevant portions covered by “Low-Level Radioactive Wastes,” H-135.966 and “Risks of Nuclear Energy and Low-Level Ionizing Radiation,” H-455.994.
H-135.982	Low Level Radioactive Wastes	Rescind. Covered by “Ionizing Radiation Exposure in the Medical Setting,” D-455.998.
H-145.994	Control of Non-Detectable Firearms	Retain. Still relevant.
H-145.995	Ban Realistic Toy Guns	Retain. Still relevant.
H-150.942	Rating System for Processed Foods	Rescind. Food label requirements have changed.
H-150.965	Eating Disorders	Retain. Still a societal issue.
H-150.975	Dangerous Health and Diet Books	Retain. Still relevant.
H-160.932	Asthma Control	Retain. Still relevant.
H-275.939	Internet Gambling	Retain in part to read as follows: Our AMA: (1) informs physicians and patients of the dangers of addiction associated with Internet gambling; (2) supports the prohibition of government-sponsored Internet gambling; and (3) in collaboration with appropriate specialty societies, pursues other avenues to and supports prohibiting the availability of Internet gambling to children.
H-280.963	Drug Regimen Review in Long Term Care Settings	Retain. Still relevant.
H-345.990	Electroconvulsive Therapy	Retain. Still relevant.
H-420.977	Posting of Warnings Against Use of Alcohol During Pregnancy	Retain. Still valid.
H-425.974	Appropriate Aspirin Use for Prevention of Heart Disease and Stroke	Retain. Still relevant.
H-425.990	Prevention of Coronary Artery Disease	Retain. Physician oversight is encouraged.
H-440.862	Immunization Access to Parents of High-Risk Infants Younger than Six Months of Age	Retain. Still relevant.
H-440.900	Treatment of Chlamydia Trachomatis	Retain. Still an issue.
H-440.901	Achieving National Adolescent Immunization Goals	Retain. An important goal.
H-440.957	Reporting Potential for Hearing Loss Due to Personal Listening Devices	Retain in part to read as follows: It is the policy of the AMA that (1) physicians counsel patients about the potential loss of hearing associated with the misuse of personal listening devices; (2) research be directed at more specific definition of the relationship between acute and chronic use of personal listening devices and the occurrence of short-term and long-term noise-induced hearing loss; and (3) the AMA work with the National Institute on Deafness and Other Communication Disorders to enhance awareness, knowledge and remediation of causes of noise induced hearing loss.
H-440.965	The Future of Public Health	Retain. Relevant to AMA mission.
H-440.997	Research and Control of Gonorrhea	Retain. Still an issue.
H-440.998	US Public Health Service	Retain. Consistent with AMA’s views.
H-440.999	Increase in Venereal Disease	Retain. Pending policy consolidation.
H-455.991	Physician Training for Management of Injuries Encountered in Nuclear Explosions Radiological Incidents	Retain in part to read as follows: The AMA supports educating and training physicians in the management of injuries that may be encountered in isolated related to radiological nuclear incidents.
H-460.910	Systemic Lupus Erythematosus Research and Its Impact on Minority Health	Retain in part to read as follows: Our AMA: (1) supports increased funding for biomedical research and educational programs that work toward finding the cause and a cure for lupus; and (2) will collaborate with medical specialty societies and federal organizations, including the Office of Research on Women's Health at the National Institutes of Health, involved with research and educational initiatives pertaining to lupus.
H-460.911	Increasing Minority Participation in Clinical Research	Retain. Still an issue.
H-460.923	Melanoma Registry	Rescind. A process is established. All states require physicians to report cases of melanoma to their central cancer registry.

H-460.930	Council on Scientific Affairs Conference: “Importance of Clinical Research: Assessing the Future in a Changing Environment”	<p>Retain in part to read as follows:</p> <p>(1) Given the profound importance of clinical research as the transition between basic science discoveries and standard medical practice of the future, the AMA will a) be the principal an advocate for clinical research; b) promote the importance of this science and of well-trained researchers to conduct it; and c) facilitate communication among different organizations and groups, including managed care organizations, that are essential for broad-based support of clinical research.</p> <p>(2) Our AMA continues to advocate vigorously for a stable, continuing base of funding and support for all aspects of clinical research within the research programs of all relevant federal agencies, including the National Institutes of Health, the Agency for <u>Healthcare Research and Quality</u> Health Care Policy and Research, the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs and the Department of Defense.</p> <p>(3) Traditional sources of financial support for clinical research and for academic health centers are diminishing significantly in the evolving health care environment of the 1990s. All endeavors that depend upon development of new knowledge and technologies for their continued success recognize the need to devote a proportion of revenue for research and development. The AMA believes it is an inherent obligation of capitation programs and managed care organizations to invest in broad-based clinical research (as well as in health care delivery and outcomes research) to assure continued transition of new developments from the research bench to medical practice. The AMA strongly encourages these groups to make significant financial contributions to support such research.</p> <p>(4) Our AMA continues to encourage medical schools a) to support clinical research; b) to train and develop clinical researchers; c) to recognize the contribution of clinical researchers to academic medicine; d) to assure the highest quality of clinical research; and e) to explore innovative ways in which clinical researchers in academic health centers can actively involve practicing physicians in clinical research.</p> <p>(5) Our AMA believes that one obligation of organized medicine and physicians is to support clinical research, as the basis of advances in medicine. To facilitate this, the AMA should explore ways physicians and physician organizations can encourage and assist in educating the public about the importance of clinical research such as through educational materials and programs for children and schools.</p> <p>(6) (5) Our AMA encourages and supports development of community and practice-based clinical research networks.</p>
H-460.973	Protection of Scientific Freedom from Special Interest Groups	Retain. Still relevant.
H-460.974	Animal Research/Rights	Rescind. Covered by “Use of Animals in Research,” H-460.979, “Increased Public Education Regarding Animal Research,” H-460.932, and “Medical Research Involving Animals,” H-460.957.
H-460.983	Availability of Funding for Research	Rescind. Covered by “Funding of Biomedical, Translational, and Clinical Research,” H-460.926 and “Support of Biomedical Research,” H-460.998.
H-460.993	Biopsychomedical Research Funding	Rescind. Covered by “Funding of Biomedical, Translational, and Clinical Research,” H-460.926 and “Support of Biomedical Research,” H-460.998.
H-470.976	Abuse of Anabolic Steroids	Retain. Still an issue.
H-470.983	Boxing as a Health Hazard	Retain. Still an issue.
H-470.993	Weight Loss in Amateur Wrestling	Retain. Still an issue.
H-470.998	Youth Physical Fitness	Retain. Still an issue.
H-480.962	Patient Access to Devices Pending Approval	Rescind. Processes are in place for expanded access to medical devices.
H-490.911	Smoke-Free America	Retain. Still relevant.
H-495.976	Opposition to Exempting the Addition of Menthol to Cigarettes	Retain in part to read as follows: Our AMA:

		<p>(1) will continue to support the Food and Drug Administration (FDA) legislation as amended by the House of Representatives and urge its passage and enactment as soon as possible as a major step forward in regulating tobacco products and the harm they create;</p> <p>(2) shall immediately petition the FDA to conduct inquiries and take steps to a ban on the use and marketing of menthol in cigarettes as a harmful additive, if the current bill is passed without the menthol amendment, once enacted into law; and</p> <p>(3) encourages and will assist its members to seek state bans on the sale of menthol cigarettes regardless of whether the current FDA legislation is enacted.</p>
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2. DRUG SHORTAGES: UPDATE

Reference committee hearing: see report of Reference Committee E.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS IN LIEU OF RESOLUTION 517 REMAINDER OF REPORT FILED

See Policy H-100.956

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. 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 2016 to February 2018, using the text term “drug shortages” combined with “impact,” “crisis,” “oncology,” “chemotherapy,” “antibacterial,” “pediatric(s),” “nutrition,” and “parenteral.” 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), American Society of Health-System Pharmacists (ASHP), Pew Charitable Trusts, the Association for Accessible Medicines, the Pharmaceutical and Research Manufacturers of America (PhRMA), 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 on a daily basis. A recent roundtable report developed by ASHP also was consulted as a key resource.¹

BACKGROUND

The CSAPH has issued eight reports on drug shortages.²⁻⁹ The findings and conclusions of the first five reports are summarized in CSAPH Report 2-I-15, “National Drug Shortages: Update.”⁷ The remainder of this report will update information on drug shortages since the 2017 report was developed, specifically commenting on the increase in drug shortages due to hurricanes that have impacted the pharmaceutical industry in Puerto Rico as well as other relevant policy considerations regarding manufacturer processes recently brought to light which have implications for the United States health care system.

CURRENT TRENDS IN DRUG SHORTAGES

Drug shortages remain an ongoing public health concern in the United States. Although the rate of new shortages has decreased, long-term active and ongoing shortages are not resolving and critical shortages are impacting patient care and pharmacy operations. Several commonly used products required for patient care are in shortage including sterile infusion solutions (e.g., saline, amino acids, dextrose), as well as diazepam, lidocaine, hydromorphone, and morphine.¹⁰⁻¹²

Ongoing supply challenges of certain medications, typically injectable products that are off-patent and have few suppliers, persist. Causes of these shortages continue to remain largely unchanged and are mostly triggered by quality problems during manufacturing processes.

As noted in previous Council reports, 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. According to the most recent data compiled by ASHP and the University of Utah Drug Information Service, the total number of new shortages in 2017 was 146 (compared with 154 in 2016) and the number of active shortages was 183 in quarter four of 2017. As of the end of 2017, the largest number of shortages belongs to the class of electrolytes, nutrition, and fluids; for 3% of the shortages, the reported reason was “natural disaster” (Appendix). The most recent metrics reported by the FDA are listed in the 2017 Drug Shortages: Update report.⁹ Updated metrics from the FDA are anticipated in summer of 2018.

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 ability for physicians to report a drug shortage (Box 1). The ASHP drug shortage resource center provides a list of shortages and some guidance on managing critical shortages (Box 1).

STATE OF THE INDUSTRY

The U.S. Government Accountability Office (GAO) examined shortages of sterile injectable anti-infective and cardiovascular drugs in 2012, 2013, and 2014 and noted that the shortages were strongly associated with three factors:

1. A decline in the number of suppliers
2. Failure of at least one establishment making a drug to comply with manufacturing standards resulting in a warning letter
3. Drugs with sales of a generic version

These factors suggest that shortages may be triggered by supply disruptions and by market forces in which there are low profit margins for generic drugs, resulting in manufacturers being less likely to increase production.¹¹

Legislation enacted in 2012, the Food and Drug Administration Safety and Innovation Act (Title X: Drug Shortages) (FDASIA) requires drug manufacturers to notify the U.S. Food and Drug Administration (FDA) “of any change in production that is reasonably likely to lead to reduction in supply” of a covered drug in the United States. Although this warning requirement has played a significant role in reducing the number of drug shortages, it has not solved the problem.¹³

Impact of Hurricanes Irma and Maria on Drug Manufacturing in Puerto Rico

In late 2017, major hurricanes struck Puerto Rico which houses significant infrastructure for manufacturing critical pharmaceutical and other medical products for worldwide distribution, including the United States. The FDA has issued multiple statements regarding the manufacturing situation in Puerto Rico. Extensive efforts have been undertaken to avoid exacerbating critical drug shortages and addressing challenges related to refrigeration, storage and transportation. FDA also has been working to relocate production in coordination with federal and local government colleagues and pharmaceutical companies. Additionally, the agency is paying particularly close attention to the demand for empty containers, which are also produced on the island, as an alternative to filled infusion bags.^{14,15}

A primary concern is the shortage of small-volume parenteral solution (SVP) products, including saline, due to production and supply-chain problems on the island. ASHP and the University of Utah Drug Information Service have developed a clinical resource on the conservation and management of SVPs (Box 1).¹⁶ Additionally, emergency physicians from Brigham and Women’s Hospital recently published an oral rehydration protocol for use to conserve sterile infusion fluids.¹⁷

ASHP DRUG SHORTAGES ROUNDTABLE

In November 2017, AMA took part in an ASHP-convened meeting to review and identify new opportunities to address ongoing supply chain and patient-care challenges associated with drug product shortages. The meeting served as a

forum for several health care organizations to examine how FDASIA has impacted shortages and to address whether a need exists to build on the law with new recommendations.

FDA Drug Shortage Program Update

An update provided by staff from the FDA Drug Shortage Program confirmed that the notification requirement enacted as part of FDASIA is generally being followed and that most companies report to the agency when they anticipate or experience problems that may lead to a shortage. A few companies have failed to comply with reporting requirements suggesting the need for additional manufacturer education regarding their reporting responsibility. Timely notification enables the FDA to create solutions intended to prevent the onset of a shortage (e.g., work with other manufacturers behind the scenes to ramp up production, expedite the review of an abbreviated new drug application (ANDA) from another company, develop a work around for the production issue, or begin the process of controlled importation of a drug to meet demand). FDA staff reiterated that the requirement for manufacturers to notify the FDA does not obligate them to disclose the problem for the interruption, its expected duration, or an estimated time frame for resolution. Additionally, under current US law, the agency cannot require a company to manufacture a drug, no matter how critical or life-sustaining it is.

While the FDA encourages companies to develop drug shortage contingency plans, few have them. More could be done to incentivize companies to develop such plans and establish manufacturing redundancy.

Outsourcer Compounding Facilities

In 2013, legislation was enacted to provide more regulatory oversight of compounding. The law created a new category of compounder, an outsourcing facility, which is regulated under Section 503B of the Food, Drug and Cosmetics Act. This category allows firms that compound drugs without a patient-specific prescription to be licensed and inspected by the FDA rather than the state board of pharmacy. These firms are not classified as pharmacies but more closely resemble drug manufacturers in their operation.

Several issues were discussed at the roundtable regarding 503B facilities and their ability to provide specific formulations in the event of drug shortages. It can take up to six weeks for 503B facilities to increase or begin production of a drug in shortage and they can do so only after the FDA adds the product to the shortage list. Because the products in short supply and the duration of the shortage cannot be predicted, not only can delays exist in initiating production, but inconsistent fulfillment from 503B facilities is common. Additionally, many 503B facilities are not able to produce drugs from active pharmaceutical ingredients (APIs) and only repackage other commercially available formulations. Adding to this complication, 503B facilities currently cannot repackage SVPs because the empty bags needed to do so are also in shortage.

Several 503B outsourcing facilities have been issued an FDA Form 483, the FDA inspection review form issued to manufacturers at the conclusion of an inspection when an investigator(s) has observed any condition that may constitute a violation of the Food Drug and Cosmetic (FD&C) Act and related Acts.¹⁸ However, no additional information is posted if or when a facility successfully addresses the deficiency detailed in the report. The uncertainty surrounding manufacturing quality among these facilities creates uncertainty for hospitals that may choose to rely on them to mitigate drug shortages.

Drug Manufacturing as Critical Infrastructure

The term “critical infrastructure” is defined in the USA Patriot Act of 2001 as “systems and assets, whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on security, national economic security, national public health or safety, or any combination of those matters.”¹⁹ Flowing out of Presidential Policy Directive 21 (PPD-21), titled Critical Infrastructure Security and Resilience, was the drafting of an update to the National Infrastructure Protection Plan (NIPP), published by the Department of Homeland Security (DHS). This update, titled NIPP: 2013, describes a national effort to identify and achieve critical infrastructure security and resilience and manage risk through partnership efforts and information sharing between public and private organizations.²⁰ Because the United States critical infrastructure is largely owned by the private sector, managing risk to enhance security and resilience needs to be a shared priority for industry and government. The Healthcare and Public Health (HPH) Sector-Specific Plan (SSP) tailors the strategic guidance provided in the NIPP to the unique operating conditions and risk landscape of the HPH sector.²¹ The HPH SSP outlines

how public and private sector partners will evaluate risks; coordinate plans and policy; and provide guidance to prevent, protect, mitigate, respond to, and recover from all hazards that pose a threat to the HPH sector critical infrastructure.

At the roundtable, the Office of the Assistant Secretary for Preparedness and Response (ASPR), Office of Emergency Management, part of the U.S. Department of Health & Human Services (DHHS), outlined its efforts to coordinate with DHS and public and private sector organizations involved in disaster response. The DHS list of critical infrastructure, which includes the HPH sector, and criteria for determining the vulnerability of the infrastructure, may be re-examined in the near future; the current plan has very specific parameters and few are HPH-related.

The discussion with ASPR focused on the potential for evaluating manufacturer locations and their cybersecurity as criteria for determining risk and inclusion within the list of critical infrastructure. The fact that several manufacturers were impacted by cyber events over the past year and that product shortages were worsened by the recent hurricanes impacting Puerto Rico, highlight the need to evaluate risk and hazard and disaster response for drug and medical product manufacturing. However, production location for specific drugs and other medical products is proprietary information and many manufacturers are unwilling to share this with DHHS and/or DHS. ASPR wants to work more closely with manufacturers and explain the benefits of information sharing and being included as critical infrastructure. Of note is that any information shared with DHS or DHHS is, by law, protected from public disclosure and used only in the context of preparedness planning and response. Additionally, DHHS in collaboration with DHS can provide analytical tools to help manufacturers prepare for disasters, identify their dependencies such as power and water, and become more resilient.

Automation Difficulties

Many of the drugs currently in shortage are basic products required for patient care in all medical settings, such as saline and SVPs. Shortages of these basic products, and their containers, are significantly affecting patient care and healthcare providers because options to address these shortages are limited or risky.

Increasing automation and the use of informatics in hospitals and large healthcare centers has created efficiencies, but the use of devices such as infusion pumps and the utilization of electronic health records (EHRs) can be associated with problems in the case of drug shortages. Many devices are often designed to use specific products from specific manufacturers. When the required product is not available and alternatives must be used, it is burdensome and requires significant work to change parameters for device functionality, if it is possible at all. Many EHRs have specific drugs and doses prepopulated for streamlining patient care and care team collaboration. When shortages occur and other drugs or doses are the only options available, EHRs must be reprogrammed with the new options, often at each EHR station and for each patient individually.

Recommendations Resulting from the Roundtable

Eleven recommendations were crafted as a result of discussions at the roundtable (Box 2). Some of them are already reflected in current AMA policy on drug shortages including urging manufacturers to establish contingency plans or redundancies in production and requiring FTC review of manufacturer mergers to evaluate shortage risk. Other recommendations include a call for greater manufacturer transparency, more information on the quality of outsourcing compounding facilities, and the examination of drug shortages as a national security initiative resulting in the addition of vital manufacturing sites as critical infrastructure.

IMPACT OF SHORTAGES ON HEALTH CARE PRACTICE

ISMP Practices Survey

ISMP recently published the results of a drug shortage survey they conducted in late 2017, before natural disasters exacerbated the shortage problem.²² Almost all respondents of the survey practiced in a hospital setting. Shortages were reported across all treatment categories. Approximately 55% of respondents indicated experiencing shortages involving more than 20 drugs within the last six months and most (66%) were affected by at least one shortage daily.

The survey results revealed concerning trends:

- Approximately 90% of respondents experienced rationing, restricting, and hoarding of drug supplies.

- Many commented on waste (for example, 250ml bags of insulin but only a small fraction is needed).
- Survey participants noted other strategies that are being employed including re-deploying medications used for crash carts, reusing vials, extending hang times for IVs, purchasing sterile products compounded from non-sterile ingredients from compounding pharmacies without evaluating the risk, and transitioning infusion devices to push IVs (changing nurse protocols).
- 15% admitted to purchasing drugs in short supply at great cost from a secondary gray market.

Most survey participants (71%) were unable, at times, to provide patients with the recommended drug or treatment for their condition due to shortages, which resulted in patients receiving a less effective drug and delayed treatments. Many participants also stated that they need full-time staff to manage drug shortages and commented that the tasks associated with this process reduce the time available for direct patient care. Additionally, many respondents provided examples of how recent drug shortages have led to unsafe practices that have increased the risk of, or contributed to, a medication error.

SUMMARY

Although recent natural disasters have increased the number of drug shortages only slightly, shortages of basic products such as saline and SVPs, and their containers, are significantly impacting the health care system by affecting patient care, increasing the potential for drug errors, and influencing the manner in which health care teams function. Box 1 is a compilation of resources available to assist physicians and hospitals in mitigating drug shortages.

Information and discussion at an ASHP-convened roundtable on current issues regarding drug shortages illuminated additional relevant policy considerations such as manufacturer transparency regarding production location and the cause(s) of shortages, quality of outsourcer compounding facilities, and the potential inclusion of vital drug manufacturing sites as critical infrastructure.

Given its role as the leading advocacy organization for physicians and a key advocate for patients, patient care, and the public health, our AMA is concerned about the shortages of basic medical supplies such as sterile saline, medications for which the vehicle for intravenous administration is sterile saline, and any containers for sterile saline or injectable medications which are a component of our nation's drug shortage problems. The AMA welcomes the application of critical infrastructure terminology and policies to the drug shortage challenges clinicians face each day.

RECOMMENDATION

The CSAPH recommends that Policy H-100.956 be amended by addition and deletion to read as follows:

National Drug Shortages

1. 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 ~~experience drug shortages~~, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.
2. 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.
3. 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.
4. 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.
5. 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.
6. 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.
 7. 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.
 8. 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.
 9. 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.
 10. 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.
 11. Our AMA encourages electronic health records (EHR) vendors to make changes to their systems to ease the burden of making drug product changes.
 12. Our AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities.
 13. 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.
 14. 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.

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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)
6. [US Department of Health and Human Services' Office of the Assistant Secretary for Preparedness and Response](#)
7. [ISMP newsletter](#) on managing drug shortages
8. American Society for Parenteral and Enteral Nutrition [guidance](#) on shortages with parenteral nutrition components
9. [NEJM article](#) detailing Brigham and Women's Hospital Oral Rehydration Protocol¹⁷

Box 2. Recommendations resulting from the ASHP Drug Shortages Roundtable.

1. Manufacturers should provide the FDA with more information on the causes of the shortages and their expected durations.
2. Establish best practices for high-alert drugs.
3. FDA should require manufacturers to establish contingency plans and/or redundancies.
4. FDA should establish incentives to encourage manufacturers to produce drugs in shortage.
5. FDA should provide more information on the quality of outsourcing facilities' compounding.
6. Reconsider the purchasing process of saline.
7. Manufacturers need to be more transparent.
8. Examine drug shortages as a national security initiative.
9. Request electronic health records (EHR) vendors to employ changes to their systems to ease the burden of making drug product changes.
10. FDA should establish a quality manufacturing initiative.
11. FTC should include in its review of drug company merger proposals the potential risk for drug shortages.

Figure 1.

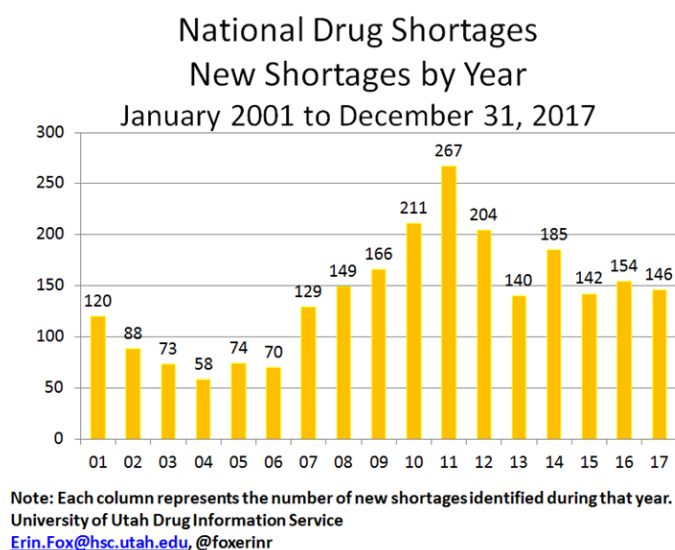


Figure 2.

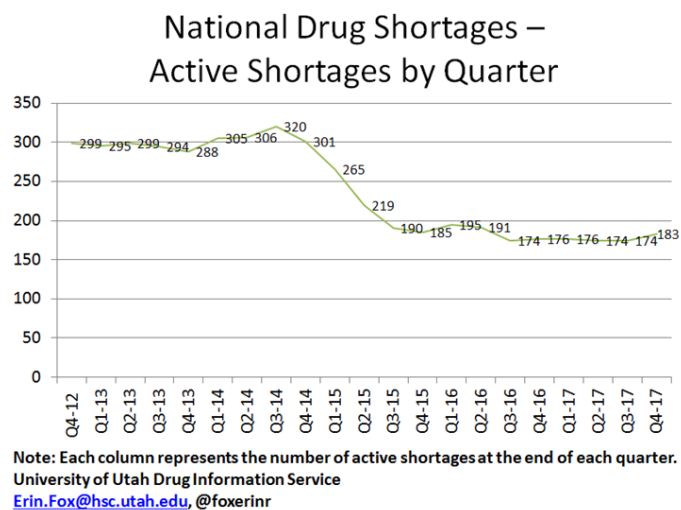


Figure 3.

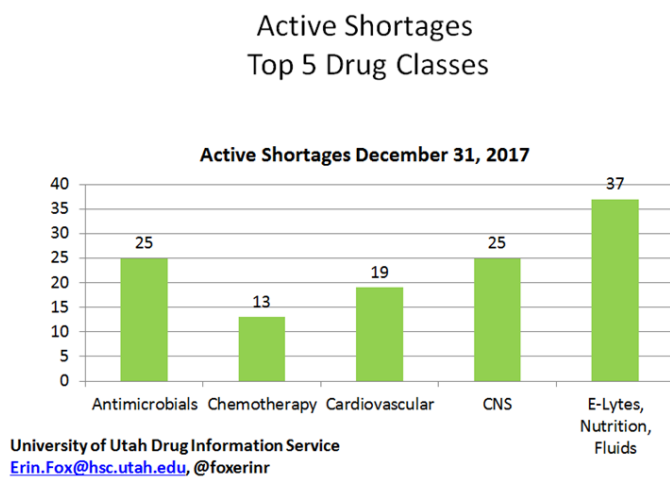
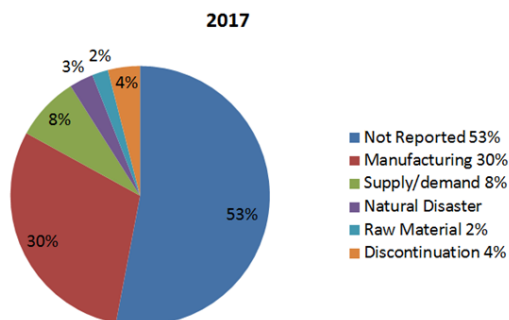


Figure 4.

Reasons for Shortages as Determined by UUDIS During Investigation



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3. PRESCRIPTION DRUG DONATION (RESOLUTIONS 207-I-17 AND 525-A-17)

Reference committee hearing: see report of Reference Committee E.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
IN LIEU OF RESOLUTIONS 201-I-17 AND 525-A-17
REMAINDER OF REPORT FILED
*See Policy H-120.925***

Resolution 207-I-17, “Redistribution of Unused Prescription Drugs to Pharmaceutical Donation and Reuse Programs,” introduced by the Medical Student Section and referred by the House of Delegates asked:

That our American Medical Association work with appropriate stakeholders to draft and promote model legislation aimed at developing better funding for drug donation programs on the state level provided these programs follow the quality assurance guidelines set by existing AMA Policy H-280.959.

Resolution 525-A-17, “Providing for Prescription Drug Donation,” introduced by the Organized Medical Staff Section and referred by the House of Delegates asked:

That our American Medical Association advocate for new federal legislation that would allow: 1) nursing homes to recycle prescription drugs that are unused, sealed, and dated; 2) physician offices and clinics to donate prescription drugs that are unused, sealed, and dated to patients in need who are uninsured or underinsured; and, 3) cancer programs and clinics to accept and recycle cancer-specific drugs to patients in need who are uninsured or underinsured.

Both of these resolutions reflect concerns about the intersection of rising drug costs, wastage and expiration of unused pharmaceutical products prompting their disposal, and existing problems with patient access and their ability to pay for needed therapies.

The Council previously examined the issue of pharmaceutical expiration (and beyond use) dates and their clinical and fiscal consequences.¹ Expiration and beyond use dates are tangentially related to prescription drug donation and/or recycling because they are fundamental criteria used to establish or reaffirm the integrity of returned products.

A fundamental goal expressed by both resolutions is minimizing the quantity of unused prescription medications while decreasing healthcare costs. A prevailing issue is how unused prescription medications that have been dispensed can be safely returned and reused. One way to lessen prescription drug waste on the front end is for physicians and other prescribers to limit quantities of prescription medications for acute therapy and/or during the initiation (trial phase) of drug treatment for a chronic condition when the safety and efficacy of such treatment is being evaluated. The other approach, which is the focus of this report, is to recycle and re-dispense unused medications.

CURRENT AMA POLICY

The AMA has well developed policy on the recycling of nursing home drugs based on a Council report issued in 1997.² At the time, it was estimated that nearly 7% of monthly medication costs were going to waste in this setting due to patient death, discontinuation of medication, a change in medication, patient transfer or hospitalization. Policy H-280.959, “Recycling of Nursing Home Drugs,” supports the return and reuse of medications to the dispensing pharmacy to reduce waste associated with unused medications in long-term care facilities (LTCFs) provided the following conditions are satisfied:

- The returned medications are not controlled substances.
- The medications are dispensed in tamper-evident packaging and returned with packaging intact (e.g., unit dose, unused injectable vials and ampules).
- In the professional judgment of the pharmacist, the medications meet all federal and state standards for product integrity.
- Policies and procedures are followed for the appropriate storage and handling of medications at the LTCF and for the transfer, receipt, and security of medications returned to the dispensing pharmacy.

- A system is in place to track re-stocking and reuse to allow medications to be recalled if required.

CURRENT STATUS OF PRESCRIPTION DRUG DONATION/REUSE PROGRAMS

Complicating the issue of recycling or medication reuse is guidance from the U.S. Food and Drug Administration (FDA) (CPG Sec. 460.300, “Return of Unused Prescription Drugs to Pharmacy Stock”) that states:

A pharmacist should not return drugs products to his stock once they have been out of his possession. It could be a dangerous practice for pharmacists to accept and return to stock the unused portions of prescriptions that are returned by patrons, because he would no longer have any assurance of the strength, quality, purity or identity of the articles.

Furthermore,

The pharmacist or doctor dispensing a drug is legally responsible for all hazards of contamination or adulteration that may arise, should he mix returned portions of drugs to his shelf stocks. Some of our investigations in the past have shown that drugs returned by patrons and subsequently resold by the pharmacist were responsible for injuries.

The language from the compliance guide is advisory in nature.

While Resolution 525-A-17 seeks federal legislation to support the recycling of “nursing home drugs,” both medical and pharmacy practice are regulated by the states. Our AMA supports state regulated medical and pharmacy practice. Increasingly state legislation, federal legislation, and regulations affecting activities of the FDA (e.g., risk evaluation and mitigation strategies) and certain policies implemented by payers, pharmaceutical benefit management companies, and pharmacy chains are restricting prescriber behavior, especially with respect to the use of opioid analgesics and other controlled substances. With respect to the specific issues raised in this report, states regulate such activities, therefore the federal approach advocated for in Resolution 525-A-17 is not further evaluated or recommended.

National Association of Boards of Pharmacy Position Statement and Model Legislation

Resolution 207-I-17 seeks to draft and promote model legislation aimed at developing better funding for drug donation programs on the state level, as long as such programs follow the quality assurance guidelines described in Policy H-280.959. In October 2012, the National Association of Boards of Pharmacy (NABP) convened a task force on “Drug Return and Reuse Programs” to develop a position statement and revise its model act that addresses “the circumstances in both the community setting and in state-mandated-repository programs under which previously dispensed medications may be re-dispensed to patients.”³

Return and Reuse of Prescription Drugs. NABP “endorses the return and reuse of medications that have been maintained in a closed system.” A closed system is defined as the “delivery to and/or return of prescription medication from a healthcare or other institutional facility, which is maintained in a controlled environment under a health care practitioner and not the patient.” This approach helps ensure the integrity of the medication. Prescription drugs should only be returned and reused when the drugs were removed from the pharmacy for delivery by pharmacy staff, a pharmacy contracted delivery service, or approved common carrier and the drugs were returned immediately, either because they were “not deliverable” or the patient refused to accept the delivery. Additionally, the returned product must remain packaged in the manufacturer’s original, sealed, and tamper-evident packaging, or the dispensing pharmacy’s original packaging. If an approved common carrier is used, product quality also must meet United States Pharmacopeia (USP) standards. Additional criteria that must be met for return and reuse include:

- All returned packaging must indicate that product integrity and stability has been maintained.
- All returned packaging must have been returned on the same day as the attempted delivery and must be evaluated to ensure it is not adulterated or could be considered misbranded.
- A state-licensed pharmacist must verify compliance with all of the above elements.

Prescription Drug Repository Programs. In contrast to the limited and unique circumstances described for a “return and reuse” program, a prescription drug repository program would be able to accept drugs that are not confined to a delivery service. Although NABP “does not endorse the reuse of medications that have left closed distribution

systems,” for states that establish repositories, such programs should be registered and under the jurisdiction of the Board of Pharmacy and be subject to inspection. Strict criteria would apply to the policies, procedures and qualification of acceptable medications for reuse. Controlled substances are not accepted, and the medication must be judged to be unadulterated, unexpired, and in unopened unit dose or manufacturer’s tamper-resistant original packaging. Additionally, such drugs must have been originally dispensed by a pharmacist or practitioner acting within their scope of practice, and upon return be kept in a separate inventory and undergo monthly expiration date review with record keeping.

In recent years, several states have legalized and implemented charitable return and reuse programs involving drugs obtained from various donation sources. According to the 2018 Survey of Pharmacy Law, 42 states currently have authorized prescription drug repository programs.⁴ A few states that have not authorized repository programs allow return and reuse; with few exceptions, states that have authorized repositories also allow return and reuse. In some cases repositories are operational only for long term care facilities and/or correctional institutions, or charitable recipients, or the program only accepts products directly from wholesalers, distributors, or hospitals; in some cases medications are accepted from outpatients. In general, the provisions in enacted legislation are comparable to the requirements contained in the NABP model legislation. Differences may exist regarding which non-controlled drugs are accepted, criteria for eligible donors and recipients, protocols for transfer and repackaging, whether the program is centralized or de-centralized, and how it is funded. A 2016 summary of state prescription drug return, reuse, and recycling laws compiled by the National Conference of State Legislatures (NCSL) concluded that nearly half of the enacted laws were not operational. Some “common obstacles are the lack of awareness about the programs, no central agency or entity designated to operate and fund the program, and added responsibilities for repository sites that accept donations.”⁵ A summary of relevant state laws with links to their operational sites is maintained by NCSL.⁵

A sampling of reports that are available on the success of such programs includes the following:

- Established in 2007, the Iowa program has served 70,000 patients and redistributed \$15 million in free medications and supplies over the last decade.⁶ Recipients at or below 200% of the federal poverty level as well as individuals who are uninsured or under-insured are eligible to receive donated drugs in their original sealed container or in tamper-evident packaging.
- Since beginning in 2007, the Wyoming program has helped residents fill more than 150,000 prescriptions (worth more than \$12.5 million).^{7,8} In 2016, the program provided more than \$2.4 million worth of donated prescription medications free of charge on a short term basis.
- Oklahoma law allows the transfer of drugs from nursing homes to the Tulsa County Pharmacy. Since the start of the program in 2004 through January 2018, more than 223,000 prescriptions at a savings of \$22 million have been dispensed.⁹
- In California, Supporting Initiatives to Redistribute Unused Medicine (SIRUM) was established. SIRUM is an online community matching drug donations with low-income safety-net health clinics whose patients could benefit from the medications.¹⁰ Unexpired drugs are collected from manufacturers, wholesalers, pharmacies and health facilities. Medicines go to clinics and pharmacies and are dispensed to low-income patients; more than 150,000 patients have been helped. SIRUM also operates the Colorado program which focuses on oncologic products. A few other states also either focus on cancer/immunosuppressant drugs or allow them in their repositories.

DISCUSSION

A substantial majority of states have authorized drug repository and/or return and reuse programs for prescription medications that are unexpired and in their original container or tamper proof packaging. Repository programs must address concerns with allowing donation and reuse of medications that have left controlled environments such as a pharmacy or institutional facility. Such concerns may include storage conditions affecting product integrity and issues specific to accepting drugs back into the supply chain that have left licensed entities that are part of the normal supply chain with track and trace requirements (i.e., possible counterfeiting or other substandard drug sources). Nearly half of the authorized programs in existence do not appear to be operational. Model state legislation to establish “return and reuse” or drug repository programs is available from the NABP. Such programs have the potential to provide pharmaceutical care to patients who cannot afford their medications, reduce waste and environmental disposal, and reduce healthcare costs. Several states have demonstrated measurable success in implementing these types of programs.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted in lieu of Resolution 207-I-17 and Resolution 525-A-17 and the remainder of the report be filed:

Our AMA encourages:

1. States with laws establishing prescription drug repository and/or “return and reuse” programs to implement such laws and to consider integrating them with existing recycling or disposal programs.
2. States that lack drug repository and/or “return and reuse” programs to enact such laws in consultation with their state board of pharmacy.
3. State medical associations in states where there is a prescription drug repository or a “return and reuse” program for unused medication supplies to educate physicians in their state regarding the existence of such programs.

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4. THE PHYSICIAN’S ROLE IN FIREARM SAFETY

Reference committee hearing: see report of Reference Committee D.

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS REMAINDER OF REPORT FILED

See Policies H-145.972, H-145.975, H-145.976, H-145.990 AND H-145.997

INTRODUCTION

In March 2017, the American Medical Association (AMA) and the American Bar Association co-sponsored a conference titled, “Preventing Gun Violence: Moving from Crisis to Action.” The conference was attended by members of the Council on Science and Public Health (Council) and the findings of this conference served as the impetus for developing this report as a Council initiative.

The Council previously studied the issue of preventing violence against health care workers and issued recommendations (see Policy H-515.957, “Preventing Violent Acts Against Health Care Providers”). That topic is not further addressed in this report.

METHODS

English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from January 2013 to January 2018 using the search terms “gun violence,” “firearm safety,” “firearm violence,”

“physician” and “firearm,” “physician” and “gun,” “suicide” and “gun” or “firearm,” “children” and “firearm safety,” “gun violence restraining order,” and “domestic violence restraining order.” Additional articles were identified by manual review of the reference lists of pertinent publications. Websites managed by federal and state agencies and applicable regulatory and advocacy organizations also were reviewed for relevant information.

CURRENT AMA POLICY

As one of the main causes of intentional and unintentional injuries and deaths, the AMA recognizes that firearms are a serious public health problem in the United States. The AMA has extensive policy on firearm safety and prevention of gun violence. Relevant to this report is existing policy that affirms the rights of physicians to have free and open communication with their patients regarding firearm safety and that calls on physicians to educate and counsel patients about firearm safety. AMA policy also supports increasing efforts to reduce pediatric firearm morbidity and mortality by encouraging its members to inquire about the presence of household firearms as a part of childproofing the home and routinely remind patients to obtain firearm safety locks, to store firearms under lock and key, and to store ammunition separately from firearms. AMA policy also urges Congress to provide sufficient resources to enable the Centers for Disease Control and Prevention (CDC) to collect and analyze data on firearm-related injuries in order to help prevent injury, death and the other costs to society resulting from firearms.

EPIDEMIOLOGY OF FIREARM MORBIDITY AND MORTALITY

Firearm-related deaths are the third leading cause of injury-related deaths in the United States. In 2016, more than 38,000 persons died from injury by firearms in the United States.¹ While mass shootings are horrific, they represent a small percentage of firearm-related deaths (less than 1 percent). Firearm suicide deaths, on the other hand, constitute more than 60 percent of firearm deaths, with firearm homicides accounting for approximately 35 percent, and accidental firearm deaths accounting for approximately 1.5 percent.^{1,2}

Males disproportionately bear the burden of firearm mortality, accounting for 86 percent of all victims of firearm death.² Young adults between the ages of 25 and 34 years have the highest rate of fatal firearm injury per 100,000 at 15.1, followed by those in the 15 to 24 year age group (14.4 per 100,000).² Rates of firearm homicide are highest among adolescents (8.9 per 100,000) and young adults (8.0 per 100,000) and tend to decrease with age.² Rates of firearm suicide tend to increase with age. The annual rate of firearm suicide was highest among persons aged 65 years and older (10.9 per 100,000) followed by those in the 55–64 year age group (9.4 per 100,000) and the 45–54 year old age group (9.2 per 100,000).²

Non-Hispanic blacks have the highest rates of firearm mortality overall (18.1 per 100,000), and this disparity is largely due to differences between racial/ethnic groups in firearm homicide.² Non-Hispanic whites (9.2 per 100,000) and non-Hispanic American Indian/Alaskan Native populations (7.8 per 100,000) have the highest rates of firearm suicide in the United States when compared to other groups.² Non-Hispanic white males account for the majority of firearm suicides.²

Although limited data are available to evaluate epidemiological trends for firearm-related injuries, it is estimated that more than 84,000 people suffered nonfatal firearm injuries in 2015.³ A study utilizing data from the Nationwide Emergency Department Sample identified 150,930 people in the period 2006–14 who presented alive to the emergency department (ED) with a firearm-related injury, representing an estimated 25.3 ED visits per 100,000 people. The incidence of ED visits for firearm-related injuries varied by patient age. It was the lowest among patients younger than age 10 (less than 1.5 ED visits per 100,000) and the highest among patients ages 15–29 (66.4 ED visits per 100,000).⁴ The incidence of firearm-related injuries was approximately nine-fold higher among male patients.⁴

The majority of patients who presented alive to the ED for a firearm-related injury were injured in an assault (49.5 percent) or unintentionally (35.3 percent). Attempted suicides and legal interventions accounted for 5.3 percent and 2.4 percent respectively.⁴ Among all patients presenting to the ED with a firearm-related injury, 48.0 percent were discharged home and 7.7 percent were discharged to additional care facilities, while 37.2 percent were admitted to inpatient care and 5.2 percent died during their visit.⁴ The financial burden associated with firearm-related injuries was estimated to be approximately \$2.8 billion per year.⁴

PHYSICIAN COUNSELING

Households with firearms exhibit an increased risk of experiencing a homicide, suicide, or accidental firearm death of a household member.⁵ While physicians counsel patients about a wide range of behaviors and conditions, a systematic review of the literature found that despite clinical acceptance of the need for firearm injury prevention among high-risk populations, screening and counseling to increase safety is performed by a minority of clinicians.⁶ A number of barriers exist that may contribute to the lack of physician counseling on firearm safety. These include legal barriers, the lack of training and time, low expectancy that counseling is effective, uncertainty regarding what to say to patients, and a desire to not offend patients.^{6,7} As with many other behavioral interventions, clinicians who have high confidence in, and self-efficacy toward, counseling are more likely to screen.⁶

The Law Does Not Prohibit Counseling

While a number of states have considered laws limiting what physicians are allowed to ask their patients about firearms, Florida is the only state that enacted such a law, the Firearm Owners' Privacy Act (FOPA), which prohibited health care practitioners from inquiring about the ownership of a firearm.⁸ An exception included in the law allowed practitioners who in good faith believed that the information was relevant to the patient's medical care or safety, or the safety of others, to inquire.⁸ In 2017, the Eleventh Circuit Court of Appeals overturned the law, holding that FOPA's content-based restrictions violated the First Amendment as it applies to the states.⁹

Montana, Missouri, and Minnesota have laws around the collection of firearm information by health practitioners; none of these laws prohibit counseling. Minnesota's law prohibits the commissioner of health from collecting data on individuals regarding lawful firearm ownership or data related to an individual's right to carry a weapon.¹⁰ Missouri's law prohibits health care professionals from disclosing information about the status of a patient as an owner of a firearm, unless medically indicated or necessitated.¹¹ Montana's law provides that health care providers may not refuse to provide health care to a person who declines to answer questions regarding firearm ownership, possession, or use.¹²

HIGH-RISK INDIVIDUALS

Little guidance is available regarding who should be screened for the risk of firearm injury.⁶ The American Academy of Pediatrics (AAP) recommends that pediatricians incorporate questions about the presence and availability of firearms into patient histories and counsel parents about the dangers of allowing children to have access to firearms both inside and outside of the home.¹³ Studies indicate that screening among high-risk populations may help identify patients at risk of firearm injury.⁶ Risk factors for firearm injury include suicidal ideation or intent, homicidal ideation or intent, history of violence, alcohol or drug use disorder, mental illness, and conditions impairing cognition and judgment.⁷

Intimate Partner Violence (IPV)

Firearms in a violent home increase the likelihood that IPV incidents will result in death.^{14,15} In 2013, approximately half of the 1,270 reported intimate partner homicides in the United States were committed with firearms.¹⁵ Because of this risk, laws have been enacted to remove firearms from those who commit IPV. At the federal level, the Violent Crime Control and Law Enforcement Act of 1994 prohibits individuals subject to certain restraining orders from purchasing or possessing a firearm.¹⁶ Furthermore, the Lautenberg Amendment makes it illegal for individuals convicted of misdemeanor domestic violence assault to purchase or possess firearms. However, there are a number of gaps in the federal law, including that it does not apply to non-spouse partners.

Mental Illness

According to the American Psychiatric Association, reasonable restrictions on gun access are appropriate, but should not be based solely on a diagnosis of mental disorder.¹⁷ Diagnostic categories vary widely in the symptoms, impairments, and disabilities of affected individuals and a considerable heterogeneity exists.¹⁷ Furthermore, individuals with mental illness, when appropriately treated, do not pose an increased risk of violence over the general population.¹⁸

Suicidal Ideation

Suicide is a leading cause of preventable death in the United States and firearms are among the most lethal suicide attempt methods, with nearly 9 out of 10 attempts resulting in death. In 2015, firearms were the most common method used in suicide deaths in the United States, accounting for almost half of all suicide deaths.¹⁹ Over the past 15 years, the total suicide rate has increased 24 percent from 10.5 to 13.0 per 100,000.¹⁹ The suicide rate among males has remained approximately four times higher (20.7 per 100,000 in 2014) than among females (5.8 per 100,000 in 2014).¹⁹

Physicians and other health professionals should be trained to assess and respond to individuals who may be at heightened risk for violence or suicide.¹⁷ In the context of suicide prevention, “lethal means counseling” refers to assessing whether a person at risk for suicide has access to a firearm or other lethal means and then working with them, their family, and support system to limit their access until they are no longer at elevated risk.²⁰ Counseling of suicidal patients or (for youth) their parents about restricting “lethal means” may increase rates of firearm removal from the home.⁶

Community Violence/Assault

High-risk youth presenting to an urban emergency department (ED) for assault have elevated rates of subsequent firearm violence.²¹ Nearly 60 percent of assault-injured youth report violent firearm aggression, victimization, and/or firearm injury within 2 years of their index ED visit.²¹ Among assault-injured youth seeking urban ED care, nearly 25% report having a firearm.²² Retaliation may be a significant motivation for ensuing firearm violence. This underscores the need for ED screening of retaliation risk and interventions that focus on alternative means of conflict resolution.

Childhood Injury Prevention

The most effective measure to prevent suicide, homicide, and unintentional firearm-related injuries to children and adolescents is the absence of firearms from homes and communities.¹³ The AAP encourages firearm screening as a standard part of universal injury prevention screening.⁶ Parents who possess firearms should be urged to prevent access by children because safer storage of firearms reduces injuries. Physician counseling linked with distribution of cable locks appears to increase safer storage.¹³

Cognitive Decline

Firearm access can pose a risk to cognitively-impaired individuals. It is estimated that as many as 60 percent of older people with dementia live in a home with a firearm, where there may be a greater likelihood that they are not locked or unloaded. The Alzheimer’s Association suggests screening for firearm access along with other safety topics (i.e., driving) as well as keeping firearms locked, with ammunition stored separately.²³

DISCUSSION

The federal Gun Control Act makes it unlawful for certain categories of persons to ship, transport, receive, or possess firearms or ammunition. Those categories include, but are not limited to individuals convicted of a felony; unlawful users or those with addiction involving any controlled substance; individuals adjudicated as a “mental defective” or under an order of civil commitment; individuals subject to a court order restraining them from harassing, stalking, or threatening an intimate partner or child of the intimate partner; or persons who have been convicted of a misdemeanor crime of domestic violence.²⁴ However, inconsistencies in states’ reporting of disqualifying records to the National Instant Criminal Background Check System, as well as loopholes in the requirements for background checks prior to a firearm purchase, contribute to the unsuccessful identification of people who should not have firearms. Furthermore, the background check system was designed to prevent someone from purchasing a new firearm; it does not grant the authority to remove firearms from a high-risk individual who already possesses them.²⁵ A number of policies have been developed to help address those gaps.

Temporary Firearm Transfer

Reducing access to lethal means is an effective, evidence-based method for suicide prevention. Most states allow the private transfer of firearms without a background check, but 19 states and Washington, DC, have universal background

check (UBC) laws mandating a background check whenever a firearm is transferred. While these laws make it harder for high-risk persons to acquire firearms, they could make it more difficult for patients to temporarily transfer a firearm to reduce access to lethal means.²⁶ Some UBC states have mechanisms that facilitate temporary transfers without a background check to certain persons (i.e., family members) or for certain time periods (e.g., 72 hours), but others do not.²⁷ In states with rigid UBC laws, physicians should understand existing background check requirements and exceptions so they can offer tailored advice to lower the risks facing their patient.²⁶

Gun Violence Restraining Orders (GVROs)

GVRO laws, also referred to as firearm restraining orders and extreme risk protection orders, give law enforcement, family members, or household members who observe an individual's dangerous behavior and believe it could be a precursor to violence (against themselves or others), the authority to petition a court to temporarily remove firearms from the individual's possession and prohibit them from purchasing a new firearm or ammunition.²⁸ The purpose is to target high-risk individuals on the basis of behavior, regardless of mental illness diagnosis, to reduce firearm violence.²⁹ Four states (Connecticut, Indiana, California, and Washington) have adopted this risk-based, preemptive approach to firearm removal.³⁰⁻³³ Similar laws have been introduced in 22 other states and the District of Columbia.

In 1999, Connecticut was the first state to authorize law enforcement to petition for the removal of firearms from individuals due to "a risk of imminent personal injury to himself or herself or to other individuals."³⁰ Connecticut's law was challenged in the courts, but was upheld by the Connecticut Appellate Court as not restricting the rights of law-abiding citizens to use arms in defense of their homes and thus, not in violation of the Second Amendment.³⁴

An evaluation of Connecticut's risk-warrant law shows that from 1999–2013, 762 risk-warrants were issued.³⁴ Almost all gun removal subjects were male (92 percent). Nearly half of the firearm removal cases were initiated by an acquaintance, with family members initiating 41 percent of cases, and employers or clinicians initiating eight percent of cases. Suicidality or self-injury threat was listed as a concern in sixty-one percent of cases, with the risk of harm to others a concern in thirty-two percent of cases.³⁴ Most risk-warrant subjects did not have contact with the public behavioral health system in the year before the risk-warrant was served. However, in the year following firearm removal, nearly one-third (29 percent) of risk-warrant subjects received treatment in the state system, suggesting the risk-warrant provided an entryway into needed mental health and substance use related services.³⁴ In nearly all cases (99 percent), police found and removed firearms when they conducted a search, with an average of seven firearms removed per subject.³⁴ It is estimated that there was one averted suicide for every 10 to 11 firearm removals—saving 72 lives over a 14 year period.³⁴

Firearm Safety Programs

Eighteen states have child access prevention (CAP) laws.³⁵ These laws mandate that a firearm be stored so that a child or teen (the specific age varies by state) is not able to gain easy access to the firearm. CAP laws do not typically mandate a specific storage method, although unloading the firearm and locking it up separately from the ammunition is recommended by some researchers. State CAP laws have been associated with lower rates of both accidental deaths of children and suicides among teens.³⁶

RESOURCES AND RELATED ACTIVITIES

At A-17, the House of Delegates adopted policy calling on the AMA to work with appropriate stakeholders to develop state-specific guidance for physicians on how to counsel patients to reduce their risk for firearm-related injury or death. In addition to this report, the Council is sponsoring an educational session at A-18 on "Preventing Gun Violence: What Physicians Can Do Now." The AMA is also in the process of developing an enduring continuing medical education (CME) module to help physicians navigate conversations with their patients on firearm safety. The CME module is expected to be available on the AMA's education center portal by the end of the year. The AMA is also working to provide physicians with state-specific guidance on firearm laws and how those laws interact with firearm safety counseling.

Other resources of interest include, "What You Can Do," a new initiative from University of California Davis' Violence Prevention Research Program designed to support health care providers in reducing firearm injury and death.³⁷ This initiative brings together a growing network of health care providers looking for ways to reduce firearm injury and death, with particular emphasis on addressing firearm injury for populations at elevated risk.³⁷

CONCLUSION

Households with firearms are at increased risk of experiencing a homicide, suicide, or accidental firearm death of a household member. Despite clinical acceptance of the need for firearm injury prevention among high-risk populations, screening and counseling to increase safety is performed by only a minority of physicians. A need exists for physician training to increase physician confidence and self-efficacy toward counseling around firearm safety. While existing AMA policy encourages physicians to educate and counsel patients on firearm safety, it does not specifically address the issue of suicide. Given the prevalence of firearm suicides in the United States, physicians should be trained in lethal means safety counseling as a part of their suicide risk assessment and prevention efforts. Furthermore, laws in most jurisdictions do not provide the authority to remove firearms from a high-risk individual who already possesses them. The AMA should support common-sense laws allowing for the removal of firearms from individuals whose conduct indicates a heightened risk of violence to themselves or others.

RECOMMENDATIONS

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

1. That the following policy be adopted.

Firearms and High-Risk Individuals

Our AMA supports: (1) the establishment of laws allowing family members, intimate partners, household members, and law enforcement personnel to petition a court for the removal of a firearm when there is a high or imminent risk for violence; (2) prohibiting persons who are under domestic violence restraining orders, convicted of misdemeanor domestic violence crimes or stalking from possessing or purchasing firearms; (3) expanding domestic violence restraining orders to include dating partners; (4) requiring states to have protocols or processes in place for requiring the removal of firearms by prohibited persons; (5) requiring domestic violence restraining orders and gun violence restraining orders to be entered into the National Instant Criminal Background Check System; and (6) efforts to ensure the public is aware of the existence of laws that allow for the removal of firearms from high-risk individuals.

2. That Policy H-145.975, "Firearm Safety and Research, Reduction in Firearm Violence, and Enhancing Access to Mental Health Care," be amended by addition and deletion to read as follows:

H-145.975, "Firearm Safety and Research, Reduction in Firearm Violence, and Enhancing Access to Mental Health Care"

1. Our AMA supports: a) federal and state research on firearm-related injuries and deaths; b) increased funding for and the use of state and national firearms injury databases, including the expansion of the National Violent Death Reporting System to all 50 states and U.S. territories, to inform state and federal health policy; c) encouraging physicians to access evidence-based data regarding firearm safety to educate and counsel patients about firearm safety; d) the rights of physicians to have free and open communication with their patients regarding firearm safety and the use of gun locks in their homes; e) encouraging local projects to facilitate the low-cost distribution of gun locks in homes; f) encouraging physicians to become involved in local firearm safety classes as a means of promoting injury prevention and the public health; and g) encouraging CME providers to consider, as appropriate, inclusion of presentations about the prevention of gun violence in national, state, and local continuing medical education programs. 2. Our AMA supports initiatives to enhance access to mental and cognitive health care, with greater focus on the diagnosis and management of mental illness and concurrent substance abuse disorders, and work with state and specialty medical societies and other interested stakeholders to identify and develop standardized approaches to mental health assessment for potential violent behavior. 3. Our AMA (a) recognizes the role of firearms in suicides, (b) encourages the development of curricula and training for physicians with a focus on suicide risk assessment and prevention as well as lethal means safety counseling, and (c) encourages physicians, as a part of their suicide prevention strategy, to discuss lethal means safety and work with families to reduce access to lethal means of suicide.

3. That Policies, H-145.976, "Firearm Safety Counseling in Physician-Led Health Care Teams," H-145.990, "Prevention of Firearm Accidents in Children," and H-145.997 "Firearms as a Public Health Problem in the United States - Injuries and Death" be reaffirmed.

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**5. TOBACCO HARM REDUCTION: A COMPREHENSIVE NICOTINE POLICY TO
REDUCE DEATH AND DISEASE CAUSED BY SMOKING
(RESOLUTION 403-A-17)**

Reference committee hearing: see report of Reference Committee D.

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTION 403-A-17
REMAINDER OF REPORT FILED**

See Policies H-490.917, H-495.988, H-495.972 and H-495.973

INTRODUCTION

Resolution 403-A-17, “Tobacco Harm Reduction: A Comprehensive Nicotine Policy to Reduce Death and Disease Caused by Smoking,” introduced by the Resident and Fellow Section and referred by the House of Delegates, asks:

That our American Medical Association (AMA) advocate for tobacco harm reduction approaches to be added to existing tobacco treatment and control efforts;

That our AMA educate physicians and patients on the myriad health effects of different nicotine products and emphasize the critical role of smoke and combustion in causing disease;

That our AMA encourage physicians to adopt patient-specific, individualized approaches to smoking cessation, particularly for patients with disease secondary to smoking and for patients who have otherwise failed traditional methods for smoking cessation;

That our AMA continue its focus on research to identify and expand options that may assist patients to transition away from smoking, including nicotine replacement therapies and noncombustible nicotine products (including e-cigarettes);

That the AMA reaffirm its position on strong enforcement of US Food and Drug Administration and other agency regulations for the prevention of use of all electronic nicotine delivery systems and tobacco products by anyone under the legal minimum purchase age. This shall include marketing to children, direct use or purchasing by children and indirect diversion to children. Further, that our AMA reaffirm physician education of patients to limit these products for children in any and all capacity.

The Council on Science and Public Health (Council) has issued two previous reports on electronic cigarettes, in 2010 and 2014, which helped establish our AMA’s existing policy around non-combustible tobacco products.

METHODS

English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from March 2014 to January 2018 using the search terms “tobacco” and “harm reduction,” “nicotine,” “electronic cigarette,” “e-cigarette,” “ENDS,” “noncombustible tobacco product,” “smokeless tobacco,” and “tobacco cessation.” Additional articles were identified by manual review of the reference lists of pertinent publications. Websites managed by federal and state agencies and applicable regulatory and advocacy organizations also were reviewed for relevant information.

Recognizing the dynamic nature of the research being published on this topic, the Council deemed it appropriate to summarize the findings and conclusions of the recent National Academies of Sciences, Engineering, and Medicine (National Academies) report on the “Public Health Consequences of E-Cigarettes” related to harm reduction. Articles published subsequent to the National Academies report are cited, as appropriate, in this report.

CURRENT AMA POLICY

It is the AMA’s position that all tobacco products are harmful to health, and that there is no such thing as a safe cigarette. AMA policy urges Congress to pass legislation to phase in the production of less hazardous and less toxic

tobacco, and to authorize the FDA to have broad-based powers to regulate tobacco products. AMA policy also 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 the elimination of nicotine and elimination of additives that enhance addictiveness.

AMA policy encourages physicians to use evidence-based clinical practice guidelines on smoking cessation for the treatment of patients with nicotine dependence and urges physicians to promote the use of FDA-approved smoking cessation tools and resources for their patients and caregivers. Physicians should be prepared to counsel patients about the use of electronic nicotine delivery systems (ENDS), including electronic cigarettes (e-cigarettes), the potential for nicotine addiction, and the hazards of dual use of e-cigarettes with conventional cigarettes. Our AMA also encourages further clinical and epidemiological research on e-cigarettes as well as research and evaluation on promising smoking cessation protocols that promote abrupt cessation of smoking without reliance on pharmaceutical products.

HISTORY OF TOBACCO HARM REDUCTION

Tobacco products in any form are harmful and addictive and can cause disease and death.¹ Combustible cigarettes cause the majority of tobacco-related disease and are responsible for more than 480,000 deaths in the United States each year, and for millions more living with smoking-related diseases.^{1,2} When used as intended, combustible cigarettes are addictive by design and are directly responsible for the deaths of at least half of all long-term users.³

Over the last decade, a new generation of tobacco products has entered the marketplace promising reduced exposure to toxicants in tobacco smoke and claiming to reduce the risk of cancer or other diseases.⁴ This has resulted in a renewed discussion around harm reduction policies, which aim to reduce, but not eliminate tobacco-related health risks.⁵

Public health advocates have been hesitant to support harm reduction approaches for tobacco because of a lack of trust in tobacco companies and their ability or willingness to develop products that will actually reduce risks.⁶ Several times in the last 50 years, the tobacco industry has developed a new cigarette, which it has promoted as safer. Large proportions of the smoking population switched to these products, mistakenly believing they were reducing their health risk, only to realize these were false promises.⁷ Specifically, experience with products promoted by the tobacco industry as safer in the past, such as “light” cigarettes, resulted in increased toxicant exposures with smokers compensating for reduced nicotine by smoking with greater frequency and intensity.⁶

In 2001, the Institute of Medicine (IOM, now the National Academies) assessed the science base for tobacco harm reduction. The IOM committee concluded that for many diseases attributable to tobacco use, reducing the risk of disease by reducing exposure to tobacco toxicants is feasible.⁸ However, such products have not been evaluated adequately to conclude they are in fact associated with reduced risks.⁸ Furthermore, according to the IOM, “the regulation of all tobacco products is a necessary precondition for assuring a scientific basis for determining the effects of potentially reduced-exposure products and assuring the public has current, reliable information on the risks and benefits.”⁸ Finally, the public health impact of potential reduced-exposure products is unknown because their effect on public health will depend on their biological harm and individual and community behaviors around their use.⁸

In 2005, with funding from the American Legacy Foundation and the Robert Wood Johnson Foundation, the Strategic Dialogue on Tobacco Harm Reduction (Dialogue) was formed to address critically important aspects of the harm reduction debate including research priorities, overarching strategic considerations, policy recommendations, and communication methods.⁴ Members of the Dialogue agreed on the concept of the continuum of risk, which is determined by the delivery of toxicants and nicotine.^{4,9} Nicotine replacement therapy (NRT) (i.e., “gum,” patch, and lozenge) is on the safer end, with combustible cigarettes on the more hazardous end, of the spectrum.⁴ When users of combustible cigarettes switch to smokeless tobacco products, “maximal potential reduction in harm could only occur with products that result in the lowest exposure to toxicants, are subject to government regulation, and that avoid adverse consequences such as increased initiation of tobacco use or decreased cessation.”⁴

THE CONTINUUM OF RISK

There is a spectrum of tobacco and medicinal products that are designed to deliver nicotine to the user.¹⁰ The toxicity associated with these products varies.¹⁰

FDA Approved Products for Treatment of Tobacco Use Disorder

FDA has approved several smoking cessation products designed to help users gradually withdraw from smoking by using specific amounts of nicotine that decrease over time. NRT products are safe and effective medications to help people stop smoking.¹¹ While NRT products contain nicotine in controlled amounts, they do not contain the other harmful chemicals found in tobacco products. NRT products are available over the counter and by prescription. Over-the-counter NRTs are approved for sale to people age 18 and older. They are available under various brand names (sometimes as generic products) and include transdermal nicotine patches, nicotine gum, and nicotine lozenges.¹¹ Prescription NRT is available under the brand name Nicotrol, and is available both as a nasal spray and an oral inhaler.¹¹ The FDA has approved two pharmacotherapy products for tobacco use disorder that do not contain nicotine. They are Chantix® (varenicline tartrate) and Zyban® (bupropion hydrochloride).¹¹ Both are available in tablet form and by prescription only.

Modified Risk Tobacco Product (MRTP)

MRTPs are tobacco products that are sold or distributed for use to reduce harm or the risk of tobacco-related disease associated with commercially marketed tobacco products.¹² FDA can issue an order authorizing the marketing of a MRTP if the evidence demonstrates that the product will or is expected to benefit the health of the population.¹²

The FDA has not approved any MRTPs. Applications from R.J. Reynolds Tobacco Company for their Camel Snus smokeless tobacco product and Philip Morris Products for their IQOS system with Marlboro Heatsticks (a heat not burn tobacco device) are currently under scientific review.¹² In January 2018, the FDA's Tobacco Products Scientific Advisory Committee (TPSAC) voted 8-0 with one abstention against Philip Morris' claim that the IQOS system can reduce the risks of tobacco-related diseases.¹³ In considering whether switching completely to IQOS presents less risk of harm than continuing to smoke cigarettes, the committee voted narrowly against the claim.¹³ TPSAC's recommendations and votes are not binding on the FDA.

Non-Combustible Tobacco Products

A number of non-combustible tobacco products are promoted as less harmful than combustible cigarettes. However, limited data are available on the long-term health effects of these products. E-cigarettes are among the most popular of these products. In 2014, more than 460 brands of e-cigarettes, available in >7,700 unique flavors, were being sold on the internet.¹⁴ E-cigarette liquids can expose users to toxicants, including solvents (propylene glycol and glycerol), flavorings, and other additives. Furthermore, heating and aerosolizing e-liquids can generate additional harmful substances.⁵ The FDA currently regulates smokeless tobacco and some dissolvable tobacco products. The agency has finalized a rule extending its regulatory authority to all tobacco products, including e-cigarettes, cigars, hookah, and pipe tobacco, but recently extended the deadline for agency review.

Combustible Cigarettes

There are approximately 600 known ingredients in combustible cigarettes.¹⁵ When burned, more than 7,000 additional chemicals are created, at least 69 of which are known to cause cancer, and many others are poisonous.¹⁵ Smoking leads to disease and disability and harms nearly every organ of the body. For every person who dies because of smoking, at least 30 people live with a serious smoking-related illness.¹⁶ Smoking causes cancer, heart disease, stroke, lung diseases, diabetes, and chronic obstructive pulmonary disease, including emphysema and chronic bronchitis.¹⁶ Secondhand smoke exposure contributes to approximately 41,000 deaths among non-smoking adults and 400 infant deaths annually.¹⁶ Secondhand smoke causes stroke, lung cancer, and coronary heart disease in adults.¹⁶ Infants and children who are exposed to secondhand smoke are at increased risk for sudden infant death syndrome, acute respiratory infections, middle ear disease, more severe asthma, respiratory symptoms, and slowed lung growth.¹⁶

FDA PLAN FOR TOBACCO AND NICOTINE REGULATION

In 2017, the FDA announced plans to reduce the devastating toll of tobacco use. 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.² 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.²

The Family Smoking Prevention and Tobacco Control Act of 2009 gave the FDA the authority to establish tobacco product standards that are appropriate for the protection of the public's health.¹⁷ Standards may require the reduction or elimination of an additive, constituent, or other component of a tobacco product because it is or may be harmful.¹⁸ In March 2018, the FDA issued two advance notices of proposed rulemaking, one to explore a product standard to lower nicotine in cigarettes to minimally or non-addictive levels and the other calling on stakeholders to share data, research, and information to inform the role that flavors play in initiation, use, and cessation of tobacco products.

Reducing cigarettes' addictiveness could potentially help addicted users quit more easily and help keep those who are experimenting from becoming regular smokers.² While the FDA's current plan does not include lowering nicotine levels in non-combustible tobacco products, conceptually the availability of potentially less harmful tobacco products could reduce risk while delivering levels of nicotine for adults who still want it.²

E-CIGARETTES AND HARM REDUCTION

In January 2018, the National Academies issued a report on the "Public Health Consequences of E-cigarettes." The report committee undertook a comprehensive review of the scientific literature regarding key constituents in e-cigarettes, human health effects, initiation and cessation of combustible tobacco cigarette use, and harm reduction.

In addressing harm reduction, the National Academies noted the absence of randomized controlled trials and longitudinal observational studies on the effects of switching from combustible tobacco cigarettes to e-cigarettes to reduce harm.⁵ Therefore, they relied on evidence regarding the exposure to toxicants present in e-cigarette aerosols compared with those in cigarette smoke, nicotine and toxicant exposures in e-cigarette users as an intermediate outcome, and comparisons of health effects on any health outcome from e-cigarette use compared with combustible tobacco cigarette smoking.⁵

Based on a limited number of laboratory studies comparing emissions of harmful and potentially harmful chemicals from e-cigarette devices with those from combustible tobacco cigarettes, aerosol emitted from e-cigarettes is substantially less complex than tobacco smoke.⁵ Several potentially toxic substances have been identified in e-cigarette aerosol, but at significantly lower levels than in combustible tobacco smoke.⁵ The National Academies found that "there is conclusive evidence that completely substituting e-cigarettes for combustible tobacco cigarettes reduces users' exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes."⁵

While the health effects of using e-cigarettes are not well understood, current evidence points to e-cigarettes being less harmful than combustible tobacco cigarettes.⁵ All but one of the studies reviewed by the National Academies showed significant short-term improvements in health outcomes in smokers who switched from combustible tobacco cigarettes to e-cigarettes.⁵ Thus, they concluded that "there is substantial evidence that completely switching from regular use of combustible tobacco cigarettes to e-cigarettes results in reduced short-term adverse health outcomes in several organ systems."⁵

Dual use of tobacco cigarettes and e-cigarettes is highly prevalent among adults and youth but little evidence exists about dual users' patterns of use. On dual use, the National Academies concluded that, "there is no available evidence whether or not long-term e-cigarette use among smokers (dual use) changes morbidity or mortality compared with those who only smoke combustible tobacco cigarettes" and "there is insufficient evidence that e-cigarette use changes short-term adverse health outcomes in several organ systems in smokers who continue to smoke combustible tobacco cigarettes (dual users)."⁵

No long-term studies exist comparing the health effects resulting from passive exposure to secondhand aerosol from e-cigarettes with effects in non-smokers passively exposed to tobacco smoke.⁵ A limited number of studies compared secondhand exposure to e-cigarette emissions to combustible tobacco cigarette smoke.⁵ While e-cigarette use in indoor environments exposes non-users to nicotine and particulates, it is at lower levels compared to tobacco smoke from combustible cigarettes.⁵ The National Academies concluded that, "there is moderate evidence that secondhand exposure to nicotine and particulates is lower from e-cigarettes compared with combustible tobacco cigarettes."⁵

CURRENT USE PATTERNS

In 2013 and 2014, more than a quarter (27.6 percent) of adults were current users of at least one type of tobacco product.¹⁹ A total of 8.9 percent of youths had used a tobacco product in the previous 30 days and 1.6 percent of youths

were daily users. Approximately 40 percent of tobacco users used multiple tobacco products, with cigarettes plus e-cigarettes as the most common combination.¹⁹ Although consumption of combustible tobacco products has decreased, the consumption of non-cigarette combustible tobacco and smokeless tobacco has increased.²⁰

In 2014, 12.6 percent of adults had ever tried an e-cigarette (at least one time) and 3.7 percent of adults currently used e-cigarettes.¹⁶ In 2016, 20.2 percent of surveyed high school students and 7.2 percent of middle school students reported current tobacco product use.²¹ E-cigarettes are the most commonly used tobacco product among high (11.3 percent) and middle (4.3 percent) school students.²¹ In 2018, health officials raised concerns about Juul, a brand of e-cigarette that looks like a flash drive.²² The devices are difficult to distinguish from a real flash drive and their vapor dissipates quickly making them easy to hide. Each Juul cartridge lasts about 200 puffs and has as much nicotine as an entire pack of cigarettes. “Juuling” has become widespread enough that school districts in several states have voiced concerns and, in some cases, have amended school policy to address the issue.²³

Use of e-cigarettes, hookah, non-cigarette combustible tobacco, or smokeless tobacco by youth is associated with cigarette smoking one year later.²⁴ Furthermore, the risk of progressing to conventional cigarette smoking is increased with use of multiple forms of non-cigarette tobacco, suggesting that novel tobacco products have the potential to undermine public health gains in combatting the smoking epidemic.²⁴ Among adolescent cigarette experimenters, using e-cigarettes has been positively and independently associated with progression to current established smoking, suggesting that e-cigarettes may encourage cigarette smoking in this population.²⁵ E-cigarette use among youth and young adults is a public health concern, and coordinated efforts are needed to protect young people from a lifetime of nicotine addiction.²⁶

SMOKING CESSATION

The United States Preventive Services Task Force (USPSTF) recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, provide behavioral interventions and offer FDA-approved pharmacotherapy for cessation to adults who use tobacco.²⁷ In 2015, 68 percent of adults smokers wanted to quit smoking, 57 percent had been advised by a health professional to quit, and 31 percent had used cessation counseling and/or medications when trying to quit.²⁸ Fewer than one-third of persons used evidenced-based cessation methods when trying to quit smoking.²⁸ To enhance cessation rates, health care providers should consistently identify smokers, advise them to quit, and promote the use of evidenced-based cessation treatments.²⁸

The USPSTF also examined the evidence on the use of e-cigarettes or ENDS and concluded that the current evidence is insufficient to recommend ENDS for tobacco cessation in adults, including pregnant women.²⁷ Furthermore, a large prospective study of recently hospitalized smokers (n=1357) who planned to quit found a negative association between the use of e-cigarettes after discharge and subsequent tobacco abstinence.²⁹ Not only does the intermittent and concurrent use of e-cigarettes with other cessation aids not aid quitting, it may hamper it.²⁹ The USPSTF recommends that clinicians direct patients who smoke tobacco to cessation interventions with established effectiveness and safety.²⁷

CONCLUSION

Despite reductions in combustible tobacco use, it still represents the leading cause of preventable death in the United States. A growing number of non-combustible tobacco products are thought to be less hazardous than combustibles, but limited evidence is available on their long-term health risks. The FDA has the authority to designate products as MRTP, but to date, no products have met the criteria and been approved through this pathway.

E-cigarettes are among the most widely used non-combustible tobacco products. Available evidence suggests that those who completely substitute e-cigarettes for combustible tobacco cigarettes have reduced exposure to numerous toxicants and carcinogens present in combustible tobacco cigarettes, resulting in reduced short-term adverse health outcomes in several organ systems. However, long-term studies on the health effects of e-cigarettes are lacking. Furthermore, the efficacy of e-cigarettes in reducing health risks has not been adequately evaluated in well-designed epidemiological studies and RCTs. Benefits are not realized in dual users, who in fact may be exposed to additional adverse health effects.

Significant concerns exist that novel, non-combustible products may pose a significant threat to tobacco cessation and prevention efforts. Smokers concerned about their health who see the claims for novel tobacco products may think that a safer cigarette genuinely exists, making them less inclined to try to quit smoking. Furthermore, ex-smokers may

start smoking again, thinking they can now safely consume tobacco products. Likewise, those who never used tobacco products may initiate tobacco use assuming that a safe tobacco product exists. E-cigarette use among youth and young adults is a public health concern. Available data suggest that youth who use e-cigarettes are more likely to smoke combustible cigarettes.

Evidence-based methods for tobacco cessation exist. The FDA has approved several smoking cessation products designed to help users gradually withdraw from smoking by using specific amounts of nicotine that decrease over time. The USPSTF has reviewed the evidence and recommends that clinicians ask all adults about tobacco use, advise them to stop using tobacco, provide behavioral interventions, and offer FDA approved pharmacotherapy for cessation to adults who use tobacco. More needs to be done to promote evidence-based cessation methods to those who are trying to quit smoking.

RECOMMENDATIONS

The Council recommends that the following statements be adopted in lieu of Resolution 403-A-17, and the remainder of the report be filed.

1. That Policy H-495.988, "FDA Regulation of Tobacco Products," be amended by addition and deletion to read as follows:

H-495.988 FDA Regulation of Tobacco Products

1. Our AMA: (A) ~~reaffirms its position~~ 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) ~~B~~ asserts that tobacco is a raw form of the drug nicotine and that tobacco products are delivery devices for an addictive substance; (E) ~~C~~ reaffirms its position that the Food and Drug Administration (FDA) does ~~have~~, and should continue to have, authority to regulate tobacco products, including their manufacture, sale, distribution, and marketing; (F) ~~D~~ 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) ~~E~~ urges Congress to pass legislation to phase in the production of less hazardous and less toxic tobacco, and to authorize the FDA have broad-based powers to regulate tobacco products; (H) ~~F~~ 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) ~~G~~ 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. That Policy H-495.972, "Electronic Cigarettes, Vaping, and Health: 2014 Update," be amended by addition and deletion to read as follows, with a change in title:

Electronic Cigarettes, Vaping, and Health: ~~2014 Update~~

1. Our AMA urges physicians to: (a) educate themselves about electronic nicotine delivery systems (ENDS), including e-cigarettes, be prepared to counsel patients about the use of these products and the potential for nicotine addiction and the potential hazards of dual use with conventional cigarettes, and be sensitive to the possibility that when patients ask about e-cigarettes, they may be asking for help to quit smoking; (b) consider expanding clinical interviews to inquire about "vaping" or the use of e-cigarettes; (c) promote the use of FDA-approved smoking cessation tools and resources for their patients and caregivers; and (d) advise patients who use e-cigarettes to take measures to assure the safety of children in the home who could be exposed to risks of nicotine overdose via ingestion of replacement e-cigarette liquid that is capped or stored improperly. 2. Our AMA: (a) encourages further clinical and epidemiological research on e-cigarettes; ~~3. Our AMA (b) supports education of the public on the health effects, including toxins and carcinogens of electronic nicotine delivery systems (ENDS) including e-cigarettes;~~ and (c) recognizes that the use of products containing nicotine in any form among youth, including e-cigarettes, is unsafe and can cause addiction.

3. That Policy H-495.973, “FDA to Extend Regulatory Jurisdiction Over All Non- Pharmaceutical Nicotine and Tobacco Products,” be amended by addition and deletion to read as follows:

H-495.973, “FDA to Extend Regulatory Jurisdiction Over All Non-Pharmaceutical Nicotine and Tobacco Products”

Our AMA: (1) supports the U.S. Food and Drug Administration's (FDA) proposed rule that would implement its deeming authority allowing the agency to extend FDA regulation of tobacco products to pipes, cigars, hookahs, e-cigarettes and all other non-pharmaceutical tobacco/nicotine products not currently covered by the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act; and (2) supports legislation and/or regulation of electronic cigarettes and all other non-pharmaceutical tobacco/nicotine products that: (a) establishes a minimum legal purchasing age of ~~18~~²¹; (b) prohibits use in all places that tobacco cigarette use is prohibited, including in hospitals and other places in which health care is delivered; (c) applies the same marketing and sales restrictions that are applied to tobacco cigarettes, including prohibitions on television advertising, product placement in television and films, and the use of celebrity spokespeople; (d) prohibits product claims of reduced risk or effectiveness as tobacco cessation tools, until such time that credible evidence is available, evaluated, and supported by the FDA; (e) requires the use of secure, child- and tamper-proof packaging and design, and safety labeling on containers of replacement fluids (e-liquids) used in e-cigarettes; (f) establishes manufacturing and product (including e-liquids) standards for identity, strength, purity, packaging, and labeling with instructions and contraindications for use; (g) requires transparency and disclosure concerning product design, contents, and emissions; and (h) prohibits the use of characterizing flavors that may enhance the appeal of such products to youth.

4. That Policy, H-490.917, “Physician Responsibilities for Tobacco Cessation” be reaffirmed.

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