Reference Committee K

CME Report(s)
  01* Promoting and Reaffirming Domestic Medical School Clerkship Education

CSAPH Report(s)
  01 Universal Color Scheme for Respiratory Inhalers
  02 Targeted Education to Increase Organ Donation
  03 Neuropathic Pain as a Disease
  04 National Drug Shortages Update
  05* Clinical Implications and Policy Considerations of Cannabis Use

Resolution(s)
  901 Harmful Effects of Screen Time in Children
  902 Expanding Expedited Partner Therapy to Treat Trichomoniasis
  903 Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals
  904 Educating Physicians About the Importance of Cervical Cancer Screening for Female-to-Male Transgender Patients
  905 Addressing Social Media Usage and its Negative Impacts on Mental Health
  906 Opioid Abuse in Breastfeeding Mothers
  907 Addressing Healthcare Needs of Foster Children
  908 Updating Energy Policy and Extraction Regulations to Promote Public Health and Sustainability
  909 Expanding Naloxone Programs
  910 Improving Treatment and Diagnosis of Maternal Depression Through Screening and State-Based Care Coordination
  911* State Maternal Mortality Review Committees
  912* Corrective Statements Ordered to be Published by Tobacco Companies for the Violation of the Racketeer Influenced and Corrupt Organizations Act
  913* Increased Death Rate and Decreased Life Expectancy in the United States
  914* Support of Training, Ongoing Education, and Consultation in Order to Reduce the Health Impact of Pediatric Environmental Chemical Exposures
  952 Implicit Bias, Diversity and Inclusion in Medical Education and Residency Training
  953 Fees for Taking Maintenance of Certification Examination
  954 Developing Physician Led Public Health / Population Health Capacity in Rural Communities
  955 Minimization of Bias in the Electronic Residency Application Service Residency Application
  956 House Physicians Category
  957 Standardization of Family Planning Training Opportunities in OB-BYN Residencies
  958 Sex and Gender Based Medicine in Clinical Education
  959* Lifestyle Medicine Education in Medical School Training and Practice

* included in the Handbook Addendum
REPORT 1 OF THE COUNCIL ON MEDICAL EDUCATION (I-17)
Promoting and Reaffirming Domestic Medical School Clerkship Education (Resolution 308-I-16)
(Reference Committee K)

EXECUTIVE SUMMARY

The catalyst for this report was Resolution 308-I-16, “Promoting and Reaffirming Domestic Medical School Clerkship Education,” from the Medical Student Section, which asked that our American Medical Association (AMA): 1) pursue legislative and/or regulatory avenues that promote the regulation of the financial compensation which medical schools can provide for clerkship positions in order to facilitate fair competition amongst medical schools and prevent unnecessary increases in domestically-trained medical student debt; 2) support the expansion of partnerships of foreign medical schools with hospitals in regions which lack local medical schools in order to maximize the cumulative clerkship experience for all students; and 3) reaffirm policies D-295.320, D-295.931, and D-295.937. Due to the complexity of the issues surrounding this topic, the resolution was referred.

This report considers concerns that have been raised about the availability of clinical clerkship training sites due to continuing increases in the enrollment of U.S. allopathic and osteopathic medical schools and in the absolute numbers of U.S. medical schools—as well as the growing number of foreign medical schools that seek to place their students in clerkships in U.S. institutions. These schools, which cater primarily to U.S. citizen international medical graduates (USIMGs), are generally located in the Caribbean, and are sometimes referred to as “offshore medical schools.” The educational experience of U.S. medical students could be compromised through competition with other learners for faculty attention and access to patients.

This report comprises:
• A review of state efforts to address this issue, in New York and Texas
• A summary of relevant medical school accreditation standards
• An analysis of potential implications for the physician workforce
• Consideration of legal and antitrust issues around this issue
• A review of past Council on Medical Education reports and AMA policy on this topic
• Proposed emendations to current AMA policy to strengthen and streamline the AMA’s position on this important topic

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Subject: Promoting and Reaffirming Domestic Medical School Clerkship Education
(Resolution 308-I-16)

Presented by: Lynne Kirk, MD, Chair

Referred to: Reference Committee K
(L. Samuel Wann, MD, Chair)

BACKGROUND

Clinical clerkships are required of medical school programs accredited by the Liaison Committee on Medical Education (LCME). These clerkships are conducted, at least in part, within teaching hospitals with which the medical school has an affiliation or formal agreement for instruction of its students. The clinical phase of education traditionally takes place in years three and four in LCME-accredited medical schools.
Concerns have been raised about the availability of clinical clerkship training sites due to continuing increases in the enrollment of U.S. allopathic and osteopathic medical schools and in the absolute numbers of U.S. medical schools, as well as competition for placement sites from other health professions programs, such as nurse practitioner and physician assistant programs. Further, the extensive and ongoing consolidation in the health care industry has led to closure of multiple hospital facilities, with concomitant reduction in the number of sites available for clinical education. The educational experience of U.S. medical students could be compromised through competition with other learners for faculty attention and access to patients.

A final factor (which is most pertinent to this report) is the growing number of foreign medical schools that seek to place their students in clerkships in U.S. institutions—in particular, those schools that cater primarily to U.S. citizen international medical graduates (USIMGs). Many of these institutions are located in the Caribbean, and are sometimes referred to as “offshore medical schools.” The eight largest of these institutions (by number of students certified by the Educational Commission for Foreign Medical Graduates [ECFMG] in 2013) include:

- St George’s University School of Medicine (Grenada) 891
- Ross University School of Medicine (Dominica) 815
- American University of Antigua College of Medicine (Antigua and Barbuda) 347
- American University of the Caribbean (Sint Maarten) 281
- Saba University School of Medicine (Saba) 156
- Windsor University School of Medicine (Saint Kitts and Nevis) 139
- Medical University of the Americas (Saint Kitts and Nevis) 135
- Saint Matthew’s University (Cayman Islands) 129

(Note: A full list is available in Appendix A, as adapted from Eckhert NL, van Zanten M. Overview of For-Profit Schools in the Caribbean. 2014. Foundation for Advancement of International Medical Education and Research.)

Accreditation/approval of these institutions is the purview of a variety of bodies, each with varying standards and requirements for quality of education. These include seeking recognition through the Ministry of Education or Ministry of Health of the institution’s home country, or accreditation or approval from regional agencies, such as the Caribbean Accreditation Authority for Education in Medicine and other Health Professions (CAAM-HP) and the Accreditation Commission on Colleges of Medicine, (a nonprofit organization in Ireland that inspects and accredits medical schools in countries that do not have a national medical accreditation body). As of 2023, the ECFMG will require that physicians applying for ECFMG Certification graduate from a medical school that has been “appropriately accredited”—that is, “accredited through a formal process that uses criteria comparable to those established for U.S. medical schools by the Liaison Committee on Medical Education (LCME) or that uses other globally accepted criteria, such as those put forth by the World Federation for Medical Education (WFME).”

Offshore medical schools typically do not own teaching hospitals. It is common for these students to complete their required clinical clerkships in another country, and the level of supervision and instruction provided to the medical student can vary widely. Medical students attending these schools tend to complete their required clinical clerkships in the U.S. Offshore medical schools are often willing to provide significant financial remuneration to secure slots for their students’ clerkship experiences. These funds are often an attractive source of revenue, particularly for urban hospitals/institutions in underserved areas.
In theory, U.S. medical schools could provide similar financial incentives to gain access to clinical sites or faculty. However, the cost would most likely be passed on to students in the same way such costs are covered for students who are attending offshore medical schools. This could result in raised tuition, and ultimately increase U.S. medical student debt (as noted in Resolve 1 of Resolution 308-I-16).

The buying (and selling) of clerkship slots benefits the offshore medical student seeking a clerkship as well as the offshore medical school and the stateside institution providing the clerkship. Medical schools (and medical students) in the United States, however, may be negatively affected. Data compiled from the 2012-2013 LCME Annual Medical Questionnaire (Part II) showed that, of the 136 medical school programs accredited at that time, 52.2 percent (71) saw increased difficulty in finding inpatient clinical placements for students in core clerkships. Of these schools, 25 attributed this increased difficulty in part to “competition for placement sites from offshore international medical schools” (along with other factors, including increase in class size and other U.S. schools in the region). Of the 15 states with the highest number of schools reporting such issues, 12 are in the northeast and mid-Atlantic regions and the upper Midwest.

STATE REGULATIONS

Nine states evaluate the physician’s clinical clerkships in connection with an application for licensure. In most states, clerkships for U.S. medical students must take place in hospitals affiliated with medical schools accredited by the LCME or with residency programs accredited by the Accreditation Council for Graduate Medical Education (ACGME). A number of states have special rules that apply to students of non-LCME-accredited medical schools in the Caribbean.

New York

Since 1981, the New York State Board of Regents has had in place regulations on the eligibility of students enrolled in offshore medical schools for clinical clerkships in New York hospitals. In summary, only students from offshore medical schools that have been approved by the New York State Education Department are eligible to complete clinical clerkships totaling more than 12 weeks in New York teaching hospitals. In addition, students wishing to participate in such clerkships must pass the United States Medical Licensing Examination (USMLE) Step 1 examination, and the clerkship may only occur in a teaching hospital with which the offshore medical school has an approved affiliation agreement. In addition, the teaching hospital must have a residency program accredited by the ACGME in the clerkship discipline.

The approval process for offshore medical schools, handled by the New York State Education Department, is based on an assessment of educational quality similar to a medical school accreditation review. Students from medical schools that are unapproved by the department are limited to no more than 12 weeks’ clerkship experience in New York teaching hospitals.

In 2008, New York City Health and Hospitals Corporation signed a 10-year, $10 million exclusive contract with a state-approved offshore medical school, through which the school pays $400 per student per week for training slots. Several other such schools soon entered into similar agreements with other New York institutions, and a 2009 report subsequently found that “about half of the 4,000 medical students doing third- and fourth-year rotations in New York State were from offshore medical schools.” These agreements began to raise concern among U.S.-based educators as to the availability of clerkships for their own students, as well as concerns that accreditation standing might be jeopardized if the quality of clerkship experiences was negatively affected due to the sheer number of students in a given rotation.
One challenge in evaluating these concerns is that the literature is silent with respect to the appropriate number of medical students in a clerkship or the resources needed to assure that a rotation is “adequate,” and indeed, the “adequate” number of students may change based on patient population and geographic location. To attempt to better ascertain these data, the Association of Medical Schools of New York (AMSNY) fielded a survey of clerkship directors in 2009. A second iteration of that survey is scheduled soon. The survey, which included questions on the availability of an adequate number of faculty/residents/staff and patients, as well as physical and IT resources, concluded that:

- LCME and COCA standards control the educational behaviors of accredited schools, but have no influence on hospitals seeking to enhance revenue streams through the sale of clerkship “slots” to unaccredited bidders.
- The establishment of quantitative benchmarks may help schools in negotiations with their traditional academic affiliates.
- Legislative action may be needed to assure quality training and patient safety in state- or federal-regulated care delivery-sites.

**Texas**

In April 2013, the Texas legislature passed legislation to address growing concerns that affiliation agreements between offshore medical schools and Texas hospitals and other health care facilities would limit Texas medical students’ options for clinical training. Through the enacted legislation, the following subsection was added to the state’s Education Code:

(c) The board may not issue a certificate of authority for a private postsecondary institution to grant a professional degree or to represent that credits earned in this state are applicable toward a degree if the institution is chartered in a foreign country or has its principal office or primary educational program in a foreign country. In this subsection, “professional degree” includes a Doctor of Medicine (M.D.), Doctor of Osteopathy (D.O.), Doctor of Dental Surgery (D.D.S.), Doctor of Veterinary Medicine (D.V.M.), Juris Doctor (J.D.), and Bachelor of Laws (LL.B.).

The legislation was supported by the Texas Medical Association (TMA) and the state’s medical schools, which feared a diminution in the number of clinical clerkships for its medical students, due in part to the willingness of offshore medical schools to pay for clerkships for their students. With only one exception, Texas medical schools do not pay for clerkships and are in no position financially to do so. Had the state legislation not been passed, it would have been expected that Texas medical schools would not have been able to afford to compete in paying for clerkships, thereby displacing Texas medical students from long-standing clerkships at Texas teaching hospitals. As a result, medical schools would likely have been forced to participate in bidding wars for clerkship space, and, consequently, pass on this added cost to medical students, resulting in increased tuition and likely, increased student debt. Noted one of the co-authors of the Texas legislation, “Our Texas medical students should be prioritized, and we must ensure they have access to those clinical rotations without doing anything to jeopardize that. They are our investment. [The state] invests in medical education, and we have to protect that investment.”

The TMA’s advocacy on this issue was buttressed by policy adopted in 2013, which resulted from a report of the association’s Council on Medical Education (see Appendix B). The policy stated, in part, that the TMA “strongly objects to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, our association strongly disapproves of the placement of any medical school undergraduate students in hospitals and other medical care delivery facilities that lack sufficient educational resources for the
supervised teaching of clinical medicine.” In addition, the policy states, “2. Institutions that accept
students for clinical placements should ensure that all such students are trained in programs that
meet requirements for curriculum, clinical experiences, and attending supervision as expected for
[LCME- and COCA-accredited] programs…. 3. TMA opposes extraordinary payments by any
medical school for access to clinical rotations. 4. Foreign medical students should not displace
Texas medical students in clinical training positions at Texas health care facilities. Priority should
be given to Texas medical students and other health care professionals for clinical training.”

RELEVANT LCME STANDARDS

A number of LCME standards9 are relevant to the topic of this report, including:

4.1 Sufficiency of Faculty
A medical school has in place a sufficient cohort of faculty members with the qualifications
and time required to deliver the medical curriculum and to meet the other needs and fulfill the
other missions of the institution.

5.5 Resources for Clinical Instruction
A medical school has, or is assured the use of, appropriate resources for the clinical
instruction of its medical students in ambulatory and inpatient settings and has adequate
numbers and types of patients (e.g., acuity, case mix, age, gender).

5.10 Resources Used by Transfer/Visiting Students
The resources used by a medical school to accommodate any visiting and transfer medical
students in its medical education program do not significantly diminish the resources available
to already enrolled medical students.

10.8 Visiting Students
A medical school does all of the following:
• Verifies the credentials of each visiting medical student
• Ensures that each visiting medical student demonstrates qualifications comparable to
  those of the medical students he or she would join in educational experiences
• Maintains a complete roster of visiting medical students
• Approves each visiting medical student’s assignments
• Provides a performance assessment for each visiting medical student
• Establishes health-related protocols for such visiting medical students
• Identifies the administrative office that fulfills these responsibilities

LCME requirements also provide guidance as to faculty serving as supervisors for medical students
from more than one institution. For example, a 2014 LCME white paper10 notes the following, in
part:

4. A given medical school must evaluate the quality of its education across sites, including at
the site(s) that serve(s) students from multiple schools, and must ensure and document that
comparability exists in the curricular core, including in required clinical encounters.

5. There must be sufficient patient resources and faculty numbers so that medical students from
each medical education program are able to meet their defined objectives and required clinical
encounters and have appropriate levels of supervision and assessment.
The presence of students from another school must not diminish the access to resources needed by students from a given medical school to meet the objectives of the specific course/clerkship, including appropriate patients/procedures and faculty.

6. If two or more LCME-accredited medical schools share faculty at a given instructional site, there should be coordination between the schools, for example, an agreement that each medical school will have appropriate access to needed resources to support its medical education program.

Resources include: 1) faculty with sufficient time to teach each cohort of students and to participate in relevant faculty development, 2) patients sufficient to meet the required clinical conditions specified by each medical school, and 3) appropriate facilities for the total numbers of students at the site at any given time.

LIMITATIONS ON AMA ACTIONS

The types of actions that the AMA can take are limited by antitrust considerations. That is, the AMA as a private entity cannot act in concert with others to limit competition by attempting to deny or restrict access of medical students from offshore medical schools to U.S. teaching hospitals. The AMA can, however, advocate to governmental entities for such limitations as a means to assure the ongoing quality of the U.S. medical education system. The AMA can also develop model state legislation that would reflect best practices for financial remuneration of clerkships.

PAST COUNCIL ON MEDICAL EDUCATION REPORTS AND RELEVANT AMA POLICY

The availability of clerkships for medical students has been the topic of three recent Council on Medical Education reports:

2. Report 4-I-09, “Factors Affecting the Availability of Clinical Training Sites for Medical Student Education” (http://bit.ly/2tmi4ds)

As a result of these and other reports and resolutions, the AMA has a number of policies on this topic:

3. H-295.995 (30, 31), “Recommendations for Future Directions for Medical Education”
4. D-295.320, “Factors Affecting the Availability of Clinical Training Sites for Medical Student Education”
5. D-295.931, “Update on the Availability of Clinical Training Sites for Medical Student Education”

This report includes recommendations for revisions to consolidate and streamline these policies, as shown in Appendix C.
DISCUSSION

The issue of adequate availability of clerkships for U.S. medical students can be seen in the context of larger issues—in particular, the quality and quantity of the future physician workforce. That workforce comprises both U.S. medical school graduates as well as a significant number of IMGs (both U.S. citizens and noncitizens). To clarify thinking in this regard, several questions may be posed. For example, is the quality of education/training for U.S. medical students imperiled by competition for clerkships by students from offshore medical schools? Also, are USIMGs receiving an adequate education to prepare them for residency and practice in the U.S.?

Recent literature on this topic urges increased scrutiny of offshore medical schools and their graduates. Eckhert\textsuperscript{11} writes, “Just as the Flexner Report strengthened medical education by raising standards, recommending quality improvements, and suggesting closure of weaker schools, a present-day review of the schools [in other countries] whose purpose is to train physicians for the United States could lead to recommendations for improvement and/or accreditation, educational innovations, or sanctions against poorly performing medical schools.” She argues that the U.S. must “look beyond our borders to ensure that physicians around the world obtain the best possible education. To begin this effort close to home—in the Caribbean Basin—makes good sense, because the growing number of graduates from the [offshore medical schools] there will be part of the next generation of physicians caring for the U.S. public and practicing alongside U.S.-trained physicians.”

Likewise, note Halperin and Goldberg,\textsuperscript{12} “U.S. medical education today faces a threat similar to that leading up to the Flexner Report, although this time the schools that do not meet the training standards necessary to ensure public health are outside U.S. borders. A dire emergency is approaching that could compromise American medical education.” They call for a number of potential solutions; most pertinent to this report, these include that state higher education boards “deny students of proprietary offshore schools access to clinical education in U.S. teaching hospitals unless these schools meet accreditation standards equivalent to those expected of U.S. medical schools.” In addition, they urge additional legislation at the state level, similar to that passed in Texas in 2013, described above.

Related to the second question posed above, the educational standards of offshore medical schools are a topic of some concern—particularly as students at these institutions are able to obtain federal funding. Attrition (and tuition) rates are high, and educational resources often lack in comparison to those at LCME-accredited medical school programs. Norcini et al. raised concerns about “striking” gaps in clinical performance among practicing USIMGs versus their non-citizen IMG and U.S. medical school graduate counterparts, and proposed further research “to clarify whether [USIMG] performance is a result of their medical education experiences or their ability. To the degree that it is the former, U.S. citizens will need information about international medical schools on which to base their application decisions. To the degree that it is the latter, and as additional training opportunities become available for U.S. citizens, medical schools and residency programs will need to be more vigilant in their selection procedures and not accept students who lack the ability to perform as physicians.”\textsuperscript{13}

As to the resolve clauses of Resolution 308-I-16, the AMA can pursue or support legislative and regulatory advocacy to promote fair competition amongst medical schools vying for clerkship positions. Additionally, the AMA can focus on educational quality, to include the appropriate number of students on a given clerkship at any one time, and address such educational aspects as curriculum, supervision, and procedural experience (logbooks). The AMA can work with interested
state and specialty medical associations to pursue legislation that addresses this issue and helps ensure a quality experience for all medical students.

Related to Resolve 2 of Resolution 308-I-16, fostering partnerships with hospitals that are not currently used for clinical teaching may benefit both students from offshore schools as well as U.S. students; this possibility also aligns with AMA policy on addressing geographic disparities in access to care. In fact, it may be appropriate that clerkship training slots be treated as public resources to help expand the physician workforce—particularly in underserved areas—versus being seen as the “property” of academic medical centers and teaching hospitals.

Finally, Resolve 3, which asks for reaffirmation of AMA policy, is obviated through the recommendations below, which incorporate changes to consolidate and streamline existing policy.

RECOMMENDATIONS

The Council on Medical Education recommends that the following recommendations be adopted in lieu of Resolution 308-I-16, and the remainder of the report be filed.

1. That our American Medical Association (AMA):

   1) Work with the Association of American Medical Colleges, American Association of Colleges of Osteopathic Medicine, and other interested stakeholders to encourage local and state governments and the federal government, as well as private sector philanthropies, to provide additional funding to support: a) infrastructure and faculty development and capacity for medical school expansion; and b) delivery of clinical clerkships and other educational experiences. (Directive to Take Action)

   2) Encourage clinical clerkship sites for medical education (to include medical schools and teaching hospitals) to collaborate with local, state, and regional partners to create additional clinical education sites and resources for students. (Directive to Take Action)

   3) Advocate for federal and state legislation/regulations to:

      a. Oppose any extraordinary compensation granted to clinical clerkship sites that would displace or otherwise limit the education/training opportunities for medical students in clinical rotations enrolled in medical school programs accredited by the Liaison Committee on Medical Education (LCME) or Commission on Osteopathic College Accreditation (COCA);

      b. Ensure that priority for clinical clerkship slots be given first to students of LCME- or COCA-accredited medical school programs; and

      c. Require that any institution that accepts students for clinical placements ensure that all such students are trained in programs that meet requirements for educational quality, curriculum, clinical experiences and attending supervision that are equivalent to those of programs accredited by the LCME and COCA. (Directive to Take Action)

   4) Encourage relevant stakeholders to study whether the “public service community benefit” commitment and corporate purposes of not for profit, tax exempt hospitals impose any legal and/or ethical obligations for granting priority access for teaching purposes to medical students from medical schools in their service area communities and, if so,
advocate for the development of appropriate regulations at the state level. (Directive to Take Action)

5) Work with interested state and specialty medical associations to pursue legislation that ensures the quality and availability of medical student clerkship positions for U.S. medical students. (Directive to Take Action)

2. Our AMA supports the practice of U.S. teaching hospitals and foreign medical schools entering into appropriate relationships directed toward providing clinical educational experiences for advanced medical students who have completed the equivalent of U.S. core clinical clerkships. Policies governing the accreditation of U.S. medical education programs specify that core clinical training be provided by the parent medical school; consequently, the AMA strongly objects to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, it strongly disapproves of the placement of medical students in teaching hospitals and other clinical sites that lack appropriate educational resources and experience for supervised teaching of clinical medicine, especially when the presence of visiting students would disadvantage the institution’s own students educationally and/or financially and negatively affect the quality of the educational program and/or safety of patients receiving care at these sites. (New HOD Policy)

3. Our AMA supports agreements for clerkship rotations, where permissible, for U.S. citizen international medical students between foreign medical schools and teaching hospitals in regions that are medically underserved and/or that lack medical schools and clinical sites for training medical students, to maximize the cumulative clerkship experience for all students and to expose these students to the possibility of medical practice in these areas. (New HOD Policy)

4. U.S. citizens should have access to factual information on the requirements for licensure and for reciprocity in the various U.S. medical licensing jurisdictions, prerequisites for entry into graduate medical education programs, and other relevant factors that should be considered before deciding to undertake the study of medicine in schools not accredited by the LCME or COCA. (New HOD Policy)

5. Existing requirements for foreign medical schools seeking Title IV Funding should be applied to those schools that are currently exempt from these requirements, thus creating equal standards for all foreign medical schools seeking Title IV Funding. (New HOD Policy)

6. That Policies H-255.988 (6, 23, 25), H-255.998, H-295.995 (30, 31), D-295.320, D-295.931, and D-295.937 be rescinded, as described in Appendix C to this report. (Rescind HOD Policy)

Fiscal Note: $1,000 for staff time
APPENDIX A: OFFSHORE MEDICAL SCHOOLS IN 2013, BY NUMBER OF ECFMG-CERTIFIED STUDENTS/GRADUATES

<table>
<thead>
<tr>
<th>School</th>
<th>Location</th>
<th>Number</th>
</tr>
</thead>
<tbody>
<tr>
<td>St George’s University School of Medicine</td>
<td>Grenada</td>
<td>891</td>
</tr>
<tr>
<td>Ross University School of Medicine</td>
<td>Dominica</td>
<td>815</td>
</tr>
<tr>
<td>American University of Antigua College of Medicine</td>
<td>Antigua and Barbuda</td>
<td>347</td>
</tr>
<tr>
<td>American University of the Caribbean</td>
<td>Sint Maarten</td>
<td>281</td>
</tr>
<tr>
<td>Saba University School of Medicine</td>
<td>Saba (Special Municipality of the Netherlands)</td>
<td>156</td>
</tr>
<tr>
<td>Windsor University School of Medicine</td>
<td>Saint Kitts and Nevis</td>
<td>139</td>
</tr>
<tr>
<td>Medical University of the Americas</td>
<td>Saint Kitts and Nevis</td>
<td>135</td>
</tr>
<tr>
<td>Saint Matthew’s University</td>
<td>Cayman Islands</td>
<td>129</td>
</tr>
<tr>
<td>American University of Integrative Sciences</td>
<td>Sint Maarten</td>
<td>86</td>
</tr>
<tr>
<td>University of Medicine and Health Sciences</td>
<td>Saint Kitts and Nevis</td>
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</tr>
<tr>
<td>Saint James School of Medicine</td>
<td>Saint Vincent and the Grenadines</td>
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<tr>
<td>Xavier University School of Medicine</td>
<td>Aruba</td>
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<td>Avalon University School of Medicine</td>
<td>Curacao</td>
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</tr>
<tr>
<td>Spartan Health Sciences University</td>
<td>Saint Lucia</td>
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</tr>
<tr>
<td>Trinity School of Medicine</td>
<td>Saint Vincent and the Grenadines</td>
<td>16</td>
</tr>
<tr>
<td>Aureus University School of Medicine</td>
<td>Aruba</td>
<td>12</td>
</tr>
<tr>
<td>23 additional institutions</td>
<td>varies</td>
<td>Fewer than 10</td>
</tr>
</tbody>
</table>

APPENDIX B: REPORT 3-A-12 OF THE TEXAS MEDICAL ASSOCIATION COUNCIL ON MEDICAL EDUCATION

Subject: Clinical Training Resources for Texas Medical Students
Presented by: Cynthia A. Jumper, MD, Chair
Referred to: Reference Committee on Public Health, Science, and Education

A medical school in the Caribbean is seeking to establish affiliation agreements with Texas hospitals and other health care facilities to provide clinical training for its third- and fourth-year medical students to complete their core clinical clerkships in Texas. Our council has grave concerns about the potential damaging effects of a proposal that has the risk of displacing Texas medical students from the already limited clinical training capacity in our state. Our educational institutions already have commitments to Texas students to provide reasonable access to training opportunities. Diminishing our own students’ access to clinical training in the state would negatively affect the quality and affordability of education for Texas medical students, resident physicians, and other health professionals — all who need and deserve priority access to clinical training in the state.

Economic Impact

State support for educating medical students, resident physicians, and other health professionals was severely reduced in the 2012-13 state budget. At the same time, in response to increasing physician demand, Texas medical schools plan an increase of 30 percent in enrollments by 2015. This will result in an estimated total of 3,300 third- and fourth-year medical students each year — the highest numbers ever for our state. There is also a strong potential for a new four-year medical school in South Texas. This vigorous growth in enrollments clearly dictates a need for more hospital clinical training space for our own students in the very near future.

Adding foreign medical students simultaneously with the large Texas enrollment growth will only exacerbate the shortage of clinical training space. The limited supply could result in a considerable increase in the cost of clerkships for medical schools, as is occurring in northeastern states, that could force increases in medical school tuition and related student debt as well as the displacement of our own medical students, and threaten the accreditation status of our own schools.

Benefit to the State

Recognizing that the state has only limited training capacity and the potential financial impact on Texas medical schools and students, thoughtful consideration must be given to the potential benefit to the state. Texas ranks second in the nation, behind California, in the retention of our medical school graduates in the state, at 59 percent.

In contrast, it is not known how many students enrolled in foreign medical schools would even have an interest in practicing in Texas. Substituting foreign students for Texas medical students would not benefit the state’s escalating physician workforce needs. It makes little sense for the state to invest at least $170,000 per year for each Texas medical student yet not provide for their reasonable access to core clinical clerkships in the state.

Further, as reported by the American Medical Association Medical Student Section in November 2011,
U.S. medical school accreditation standards require both a broad and significant portfolio of undergraduate experiences as well as a rigorous and specifically defined standard of preclinical education in the first two years of medical school before admitted, visiting, or transfer American medical students are allowed to participate in third year clerkships, yet for-profit offshore medical schools do not provide any standardized or equivalent system of evaluation before they participate in third year clerkships in American hospitals.

Availability of Clinical Faculty and Student Supervision Rules

Given the increases in our own medical school enrollment, it is unclear whether there are sufficient numbers of qualified clinical faculty to oversee the training of our own medical students in addition to foreign medical students. The Texas Medical Board has regulations that delineate specific requirements for physicians eligible to supervise medical students.\(^i\) The board’s rules also must be considered to ensure that medical students who complete clerkships in Texas would ultimately be eligible for medical licensure in the state.

Policy Proposals

Our council believes it is in the best interest of the state … for quality, education, workforce, as well as economic considerations … to ensure that Texas medical school students are provided first access to core clinical clerkships in the state. The council proposes adoption of the following principles as Texas Medical Association policy, including relevant policies of AMA, with their adaptation for Texas.

1. Policies governing the accreditation of U.S. medical education programs specify that core clinical training be provided by the parent medical school; consequently, the Texas Medical Association strongly objects to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, our association strongly disapproves of the placement of any medical school undergraduate students in hospitals and other medical care delivery facilities that lack sufficient educational resources for the supervised teaching of clinical medicine.

2. Institutions that accept students for clinical placements should ensure that all such students are trained in programs that meet requirements for curriculum, clinical experiences, and attending supervision as expected for programs accredited by the Liaison Committee on Medical Education or the Commission on Osteopathic College Accreditation.

3. The Texas Medical Association opposes extraordinary payments by any medical school for access to clinical rotations.

4. Foreign medical students should not displace Texas medical students in clinical training positions at Texas health care facilities. Priority should be given to Texas medical students and other health care professionals for clinical training.

Recommendation: Approval as TMA policy.


ii. Texas Medical Board Program Rule, §162.1. Supervision of Medical Students.

(a) In order to supervise a medical student who is enrolled at a Texas medical school as a full-time student or visiting student the physician must have an active and unrestricted Texas license.
(b) In order to supervise a medical student who does not meet the criteria in subsection (a) of this section the physician must:

1. have an active and unrestricted Texas license;
2. hold a faculty position in the graduate medical education program in the same specialty in which the student will receive undergraduate medical education;
3. supervise the student during the educational period; and
4. supervise the student’s medical education in either a Texas hospital or teaching institution, which sponsors or participates in a program of graduate medical education accredited by the Accrediting Council for Graduate Medical Education, the American Osteopathic Association, or the Texas Medical Board in the same subject as the medical or osteopathic medical education in which the hospital or teaching institution has an agreement with the applicant’s school.

(c) If the physician is not licensed in Texas as required in subsection (a) or (b) of this section, the physician must be employed by the federal government and maintain an active and unrestricted license.

(d) Physician applicants who receive medical education in the United States in settings that do not comply with statutory requirements set forth in Texas Occupations Code §155.003(b) - (c) may be ineligible for licensure.
APPENDIX C: RECOMMENDED ACTIONS ON HOUSE OF DELEGATES’ POLICIES RELATED TO CLERKSHIPS

H-255.988, “AMA Principles on International Medical Graduates”

Delete 6, 23, and 25, for incorporation into the proposed new policy. These three items are more relevant to the topic of availability of clinical clerkships than to principles on international medical graduates.

Our AMA supports:
1. Current U.S. visa and immigration requirements applicable to foreign national physicians who are graduates of medical schools other than those in the United States and Canada.
2. Current regulations governing the issuance of exchange visitor visas to foreign national IMGs, including the requirements for successful completion of the USMLE.
3. The AMA reaffirms its policy that the U.S. and Canada medical schools be accredited by a nongovernmental accrediting body.
4. Cooperation in the collection and analysis of information on medical schools in nations other than the U.S. and Canada.
5. Continued cooperation with the ECFMG and other appropriate organizations to disseminate information to prospective and current students in foreign medical schools. An AMA member, who is an IMG, should be appointed regularly as one of the AMA's representatives to the ECFMG Board of Trustees.
6. The core clinical curriculum of a foreign medical school should be provided by that school; U.S. hospitals should not provide substitute core clinical experience for students attending a foreign medical school.
7. Working with the Accreditation Council for Graduate Medical Education (ACGME) and the Federation of State Medical Boards (FSMB) to assure that institutions offering accredited residencies, residency program directors, and U.S. licensing authorities do not deviate from established standards when evaluating graduates of foreign medical schools.
8. In cooperation with the ACGME and the FSMB, supports only those modifications in established graduate medical education or licensing standards designed to enhance the quality of medical education and patient care.
9. The AMA continues to support the activities of the ECFMG related to verification of education credentials and testing of IMGs.
10. That special consideration be given to the limited number of IMGs who are refugees from foreign governments that refuse to provide pertinent information usually required to establish eligibility for residency training or licensure.
11. That accreditation standards enhance the quality of patient care and medical education and not be used for purposes of regulating physician manpower.
12. That AMA representatives to the ACGME, residency review committees and to the ECFMG should support AMA policy opposing discrimination. Medical school admissions officers and directors of residency programs should select applicants on the basis of merit, without considering status as an IMG or an ethnic name as a negative factor.
13. The requirement that all medical school graduates complete at least one year of graduate medical education in an accredited U.S. program in order to qualify for full and unrestricted licensure.
14. Publicizing existing policy concerning the granting of staff and clinical privileges in hospitals and other health facilities.
15. The participation of all physicians, including graduates of foreign as well as U.S. and Canadian medical schools, in organized medicine. The AMA offers encouragement and assistance to state,
county, and specialty medical societies in fostering greater membership among IMGs and their participation in leadership positions at all levels of organized medicine, including AMA committees and councils and state boards of medicine, by providing guidelines and non-financial incentives, such as recognition for outstanding achievements by either individuals or organizations in promoting leadership among IMGs.

16. Support studying the feasibility of conducting peer-to-peer membership recruitment efforts aimed at IMGs who are not AMA members.

17. AMA membership outreach to IMGs, to include a) using its existing publications to highlight policies and activities of interest to IMGs, stressing the common concerns of all physicians; b) publicizing its many relevant resources to all physicians, especially to nonmember IMGs; c) identifying and publicizing AMA resources to respond to inquiries from IMGs; and d) expansion of its efforts to prepare and disseminate information about requirements for admission to accredited residency programs, the availability of positions, and the problems of becoming licensed and entering full and unrestricted medical practice in the U.S. that face IMGs. This information should be addressed to college students, high school and college advisors, and students in foreign medical schools.

18. Recognition of the common aims and goals of all physicians, particularly those practicing in the U.S., and support for including all physicians who are permanent residents of the U.S. in the mainstream of American medicine.

19. Its leadership role to promote the international exchange of medical knowledge as well as cultural understanding between the U.S. and other nations.

20. Institutions that sponsor exchange visitor programs in medical education, clinical medicine and public health to tailor programs for the individual visiting scholar that will meet the needs of the scholar, the institution, and the nation to which he will return.

21. Informing foreign national IMGs that the availability of training and practice opportunities in the U.S. is limited by the availability of fiscal and human resources to maintain the quality of medical education and patient care in the U.S., and that those IMGs who plan to return to their country of origin have the opportunity to obtain GME in the United States.

22. U.S. medical schools offering admission with advanced standing, within the capabilities determined by each institution, to international medical students who satisfy the requirements of the institution for matriculation.

23. Providing U.S. students who are considering attendance at an international medical school with information enabling them to assess the difficulties and consequences associated with matriculation in a foreign medical school.

24. The Federation of State Medical Boards, its member boards, and the ECFMG in their willingness to adjust their administrative procedures in processing IMG applications so that original documents do not have to be recertified in home countries when physicians apply for licenses in a second state.

25. Our AMA supports the application of the existing requirements for foreign medical schools seeking Title IV Funding to those schools which are currently exempt from these requirements, thus creating equal standards for all foreign medical schools seeking Title IV Funding.

H-255.998, “Foreign Medical Graduates”

Rescind and incorporate into the proposed new policy.

Our AMA supports the following principles, based on recommendations of the Ad Hoc Committee on Foreign Medical Graduates (FMGs): Our AMA supports the practice of U.S. teaching hospitals and foreign medical educational institutions entering into appropriate relationships directed toward providing clinical educational experiences for advanced medical students who have completed the equivalent of U.S. core clinical clerkships. Policies governing the accreditation of U.S. medical education programs specify that core clinical training be provided by the parent medical school; consequently, the AMA strongly objects to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, it strongly disapproves of the placement of any medical school undergraduate students in hospitals and other medical care delivery facilities which lack educational resources and experience for supervised teaching of clinical medicine.


H-295.995, “Recommendations for Future Directions for Medical Education”

Delete 30 and 31, for insertion into the proposed new policy.

Our AMA supports the following recommendations relating to the future directions for medical education:

1. The medical profession and those responsible for medical education should strengthen the general or broad components of both undergraduate and graduate medical education. All medical students and resident physicians should have general knowledge of the whole field of medicine regardless of their projected choice of specialty.

2. Schools of medicine should accept the principle and should state in their requirements for admission that a broad cultural education in the arts, humanities, and social sciences, as well as in the biological and physical sciences, is desirable.

3. Medical schools should make their goals and objectives known to prospective students and premedical counselors in order that applicants may apply to medical schools whose programs are most in accord with their career goals.

4. Medical schools should state explicitly in publications their admission requirements and the methods they employ in the selection of students.

5. Medical schools should require their admissions committees to make every effort to determine that the students admitted possess integrity as well as the ability to acquire the knowledge and skills required of a physician.

6. Although the results of standardized admission testing may be an important predictor of the ability of students to complete courses in the preclinical sciences successfully, medical schools should utilize such tests as only one of several criteria for the selection of students. Continuing review of admission tests is encouraged because the subject content of such examinations has an influence on premedical education and counseling.

7. Medical schools should improve their liaison with college counselors so that potential medical students can be given early and effective advice. The resources of regional and national organizations can be useful in developing this communication.

8. Medical schools are chartered for the unique purpose of educating students to become physicians and should not assume obligations that would significantly compromise this purpose.

9. Medical schools should inform the public that, although they have a unique capability to identify the changing medical needs of society and to propose responses to them, they are only one
of the elements of society that may be involved in responding. Medical schools should continue to identify social problems related to health and should continue to recommend solutions.

(10) Medical school faculties should continue to exercise prudent judgment in adjusting educational programs in response to social change and societal needs.

(11) Faculties should continue to evaluate curricula periodically as a means of insuring that graduates will have the capability to recognize the diverse nature of disease, and the potential to provide preventive and comprehensive medical care. Medical schools, within the framework of their respective institutional goals and regardless of the organizational structure of the faculty, should provide a broad general education in both basic sciences and the art and science of clinical medicine.

(12) The curriculum of a medical school should be designed to provide students with experience in clinical medicine ranging from primary to tertiary care in a variety of inpatient and outpatient settings, such as university hospitals, community hospitals, and other health care facilities. Medical schools should establish standards and apply them to all components of the clinical educational program regardless of where they are conducted. Regular evaluation of the quality of each experience and its contribution to the total program should be conducted.

(13) Faculties of medical schools have the responsibility to evaluate the cognitive abilities of their students. Extramural examinations may be used for this purpose, but never as the sole criterion for promotion or graduation of a student.

(14) As part of the responsibility for granting the MD degree, faculties of medical schools have the obligation to evaluate as thoroughly as possible the non-cognitive abilities of their medical students.

(15) Medical schools and residency programs should continue to recognize that the instruction provided by volunteer and part-time members of the faculty and the use of facilities in which they practice make important contributions to the education of medical students and resident physicians. Development of means by which the volunteer and part-time faculty can express their professional viewpoints regarding the educational environment and curriculum should be encouraged.

(16) Each medical school should establish, or review already established, criteria for the initial appointment, continuation of appointment, and promotion of all categories of faculty. Regular evaluation of the contribution of all faculty members should be conducted in accordance with institutional policy and practice.

(17a) Faculties of medical schools should reevaluate the current elements of their fourth or final year with the intent of increasing the breadth of clinical experience through a more formal structure and improved faculty counseling. An appropriate number of electives or selected options should be included. (17b) Counseling of medical students by faculty and others should be directed toward increasing the breadth of clinical experience. Students should be encouraged to choose experience in disciplines that will not be an integral part of their projected graduate medical education.

(18) Directors of residency programs should not permit medical students to make commitments to a residency program prior to the final year of medical school.

(19) The first year of postdoctoral medical education for all graduates should consist of a broad year of general training. (a) For physicians entering residencies in internal medicine, pediatrics, and general surgery, postdoctoral medical education should include at least four months of training in a specialty or specialties other than the one in which the resident has been appointed. (A residency in family practice provides a broad education in medicine because it includes training in several fields.) (b) For physicians entering residencies in specialties other than internal medicine, pediatrics, general surgery, and family practice, the first postdoctoral year of medical education should be devoted to one of the four above-named specialties or to a program following the general requirements of a transitional year stipulated in the "General Requirements" section of the "Essentials of Accredited Residencies." (c) A program for the transitional year should be planned, designed, administered, conducted, and evaluated as an entity by the sponsoring institution rather than one or more departments. Responsibility for the executive direction of the program should be
assigned to one physician whose responsibility is the administration of the program. Educational programs for a transitional year should be subjected to thorough surveillance by the appropriate accrediting body as a means of assuring that the content, conduct, and internal evaluation of the educational program conform to national standards. The impact of the transitional year should not be deleterious to the educational programs of the specialty disciplines.

(20) The ACGME, individual specialty boards, and respective residency review committees should improve communication with directors of residency programs because of their shared responsibility for programs in graduate medical education.

(21) Specialty boards should be aware of and concerned with the impact that the requirements for certification and the content of the examination have upon the content and structure of graduate medical education. Requirements for certification should not be so specific that they inhibit program directors from exercising judgment and flexibility in the design and operation of their programs.

(22) An essential goal of a specialty board should be to determine that the standards that it has set for certification continue to assure that successful candidates possess the knowledge, skills, and the commitment to upgrade continually the quality of medical care.

(23) Specialty boards should endeavor to develop a consensus concerning the significance of certification by specialty and publicize it so that the purposes and limitations of certification can be clearly understood by the profession and the public.

(24) The importance of certification by specialty boards requires that communication be improved between the specialty boards and the medical profession as a whole, particularly between the boards and their sponsoring, nominating, or constituent organizations and also between the boards and their diplomates.

(25) Specialty boards should consider having members of the public participate in appropriate board activities.

(26) Specialty boards should consider having physicians and other professionals from related disciplines participate in board activities.

(27) The AMA recommends to state licensing authorities that they require individual applicants, to be eligible to be licensed to practice medicine, to possess the degree of Doctor of Medicine or its equivalent from a school or program that meets the standards of the LCME or accredited by the American Osteopathic Association, or to demonstrate as individuals, comparable academic and personal achievements. All applicants for full and unrestricted licensure should provide evidence of the satisfactory completion of at least one year of an accredited program of graduate medical education in the US. Satisfactory completion should be based upon an assessment of the applicant's knowledge, problem-solving ability, and clinical skills in the general field of medicine. The AMA recommends to legislatures and governmental regulatory authorities that they not impose requirements for licensure that are so specific that they restrict the responsibility of medical educators to determine the content of undergraduate and graduate medical education.

(28) The medical profession should continue to encourage participation in continuing medical education related to the physician's professional needs and activities. Efforts to evaluate the effectiveness of such education should be continued.

(29) The medical profession and the public should recognize the difficulties related to an objective and valid assessment of clinical performance. Research efforts to improve existing methods of evaluation and to develop new methods having an acceptable degree of reliability and validity should be supported.

(30) U.S. citizens should have access to factual information on the requirements for licensure and for reciprocity in the various jurisdictions, prerequisites for entry into graduate medical education programs, and other factors that should be considered before deciding to undertake the study of medicine in schools not accredited by the LCME.

(31) Policies governing the accreditation of U.S. medical education programs specify that core clinical training be provided by the parent medical school; consequently, the AMA strongly objects
to the practice of substituting clinical experiences provided by U.S. institutions for core clinical curriculum of foreign medical schools. Moreover, it strongly disapproves of the placement of any medical school undergraduate students in hospitals and other medical care delivery facilities which lack educational resources and experience for supervised teaching of clinical medicine.

(32) Methods currently being used to evaluate the readiness of graduates of foreign medical schools to enter accredited programs in graduate medical education in this country should be critically reviewed and modified as necessary. No graduate of any medical school should be admitted to or continued in a residency program if his or her participation can reasonably be expected to affect adversely the quality of patient care or to jeopardize the quality of the educational experiences of other residents or of students in educational programs within the hospital.

(33) The Educational Commission for Foreign Medical Graduates should be encouraged to study the feasibility of including in its procedures for certification of graduates of foreign medical schools a period of observation adequate for the evaluation of clinical skills and the application of knowledge to clinical problems.

(34) The AMA, in cooperation with others, supports continued efforts to review and define standards for medical education at all levels. The AMA supports continued participation in the evaluation and accreditation of medical education at all levels.

(35) The AMA, when appropriate, supports the use of selected consultants from the public and from the professions for consideration of special issues related to medical education.

(36) The AMA encourages entities that profile physicians to provide them with feedback on their performance and with access to education to assist them in meeting norms of practice; and supports the creation of experiences across the continuum of medical education designed to teach about the process of physician profiling and about the principles of utilization review/quality assurance.

(37) Our AMA encourages the accrediting bodies for MD- and DO-granting medical schools to review, on an ongoing basis, their accreditation standards to assure that they protect the quality and integrity of medical education in the context of the emergence of new models of medical school organization and governance.


D-295.320, “Factors Affecting the Availability of Clinical Training Sites for Medical Student Education”

Rescind and incorporate into the proposed new policy.

1. Our AMA will work with the Association of American Medical Colleges and the American Association of Colleges of Osteopathic Medical Education to encourage local and state governments and the federal government, as well as private sector philanthropies, to provide additional funding to support infrastructure and faculty development for medical school expansion.

2. Our AMA will encourage medical schools and the rest of the medical community within states or geographic regions to engage in collaborative planning to create additional clinical education resources for their students.

3. Our AMA will support the expansion of medical education programs only when educational program quality, including access to appropriate clinical teaching resources, can be assured.

4. Our AMA will advocate for regulations that would ensure clinical clerkship slots be given first to students of US medical schools that are Liaison Committee on Medical Education- or Commission on Osteopathic College Accreditation-approved, or schools currently given preliminary accreditation status, provisional accreditation status, or equivalent, from either of the above bodies.
5. Our AMA will advocate for federal and state legislation or regulations to oppose any extraordinary compensation for clinical clerkship sites by medical schools or other clinical programs that would result in displacement or otherwise limit the training opportunities of United States LCME/COCA students in clinical rotations.

D-295.931, “Update on the Availability of Clinical Training Sites for Medical Student Education”

Rescind and incorporate into new proposed policy.

1. Our AMA will work with appropriate collaborators to study how to build additional institutional and faculty capacity in the US for delivering clinical education.
2. Our AMA, in collaboration with interested stakeholders, will:
   (a) study options to require that students from international medical schools who desire to take clerkships in US hospitals come from medical schools that are approved by an independent public or private organization, such as the Liaison Committee on Medical Education, using principles consistent with those used to accredit US medical schools;
   (b) advocate for regulations that will assure that international students taking clinical clerkships in US medical schools come from approved medical schools that assure educational quality that promotes patient safety; and
   (c) advocate that any institution that accepts students for clinical placements be required to assure that all such students are trained in programs that meet requirements for curriculum, clinical experiences and attending supervision as expected for Liaison Committee on Medical Education and American Osteopathic Association accredited programs.
3. Our AMA will study whether the “public service community benefit” commitment and corporate purposes of not for profit, tax exempt hospitals impose any legal and/or ethical obligations for granting priority access for teaching purposes to medical students from medical schools in their service area communities and, if so, advocate for the development of appropriate regulations at the state level.
4. Our AMA opposes any arrangements of US medical schools or their affiliated hospitals that allow the presence of visiting students to disadvantage their own students educationally or financially.

D-295.937, “Competition for Clinical Training Sites”

Rescind; this analysis was completed through Council on Medical Education Report 2-I-08, “Update on Availability of Clinical Training Sites for Medical Student Education.”

Our AMA will, through the Council of Medical Education, conduct an analysis of the adequacy of clinical training sites to accommodate the increasing number of medical students in the US accredited medical schools and study the impact of growing pressure, including political and financial, to accommodate clinical training in US hospitals for US citizen international medical students.
(Res. 324, A-08)
### APPENDIX D: SUMMARY OF PROPOSED POLICY CHANGES

<table>
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3 Standards and process for the approval of international medical schools to place students in long-term clinical clerkships in New York State. New York Codes, Rules and Regulations. 8 CRR-NY 60.10; NY-CRR. Available at: http://bit.ly/2sy9y8x. Accessed July 7, 2017


INTRODUCTION

Resolution 906-I-16, “Universal Color Scheme for Respiratory Inhalers,” introduced by the Resident and Fellow Section and referred by the House of Delegates asked:

That our American Medical Association work with leading respiratory inhaler manufacturing companies and health agencies such as the Federal Drug Administration and the American Pharmacists Association to develop consensus of a universal color scheme for short-acting beta-2 agonist respiratory inhalers that are used as “rescue inhalers” in the United States;

That our AMA work with leading respiratory inhaler manufacturing companies to ensure the universal color scheme for respiratory inhalers would allow for the least disruption possible to current inhaler colors, taking into account distribution of each brand and impact on current users if color were to change;

That our AMA work with leading respiratory inhaler manufacturing companies to ensure that universal color scheme for respiratory inhalers be designed for adherence and sustainability, including governance for future companies entering the respiratory inhaler market, and reserving colors for possible new drug classes in the future.

Traditionally, in the United Kingdom, Canada, and parts of Europe short-acting β2-adrenergic agonist (SABA) respiratory inhalers are colored blue and referred to as “relievers” or “rescuers,” while inhaled corticosteroids (ICS) are colored brown, orange, or red and are referred to as “preventers” or “controllers.” No convention exists in the United States for the coloration of respiratory inhalers.

CURRENT AMA POLICY

Policy H-115.980, “Distinctive Labeling of Vials and Ampules, Prefilled Syringes, Ophthalmic Solutions and Related Liquid Medications,” is somewhat related to this resolution, calling for the development of appropriate guidelines aimed at developing easily identifiable labeling to optimize the safe use of liquid medication. No current AMA policy related to color coding of respiratory inhalers exists.
METHODS

English-language articles were selected from a search of the PubMed database through July, 2017 using the search term “inhaler” coupled with “color” and “colour.” Additional articles were identified from a review of the references cited in retrieved publications. Searches of selected medical specialty society and international, national, and local government agency websites were conducted to identify relevant clinical guidelines, position statements, and reports.

COLOR CODING

Color coding is the systematic, standard application of a color system to aid in the classification and identification of drug products. Conceptually, a color coding system allows users to associate a color with a function. Color coding as an aid to patient safety requires the use of consistent coloring schemes by all manufacturers.

Color Coding and Medication Errors

In a 2004 report, titled “The Role of Color Coding in Medication Error Reduction,” the Council on Scientific Affairs (CSA) (predecessor to the Council on Science and Public Health) noted controversy among experts and a variety of potential problems with color coding of pharmaceutical products, which suggest that a universal color scheme should not be universally adopted. Several organizations involved in medication error prevention, including the American Society of Health-System Pharmacists (ASHP), Institute for Safe Medication Practices (ISMP), U.S. Food and Drug Administration (FDA), and the pharmaceutical industry either oppose color coding or recommend caution in its application. The report also noted a lack of evidence proving that color coding reduces medication errors; this lack of evidence still exists.

The result of the CSA report was a directive that was sunsetted in 2014 after AMA provided testimony to the FDA regarding the report’s findings, which identified potential problems associated with the color coding of pharmaceutical products. The FDA released a draft guidance in 2013, entitled “Safety Considerations for Container Labels and Carton Labeling Design to Minimize Medication Errors.” The draft guidance recommends avoiding color coding in most instances and goes on to note that “[c]olor coding schemes developed to decrease error may actually increase error when the color is relied upon as a shortcut to proper identification (i.e., not reading the label).” FDA intends to finalize this guidance.

FDA notes limited applications of color coding that are appropriate and were established before the 2013 guidance document, such as the caps of ophthalmic solutions that indicate the therapeutic class of a drug. These classifications, however, are generally not useful to end users outside of ophthalmology and these color classifications have caused problems with users having difficulty differentiating between drugs within the same therapeutic class. Additionally, the color-coding of surgical anesthesia syringes has been adopted with the intention of reducing the risk of accidental syringe swapping by surgical users, but limited evidence has not shown that drug errors have been eliminated. In both examples, the end user populations are limited groups, not a large outpatient patient population.

Additional Disadvantages of Color Coding of Pharmaceutical Products

In addition to the lack of scientific evidence that proves color coding reduces medication errors, experts in the field of medication errors also cite other reasons why the widespread adoption of
color coding systems for pharmaceutical products should be done with great caution.\textsuperscript{1,3,5,6,9-12} Potential problems include:

- There is a limit to the number of discernable colors available for commercial use.
- Subtle distinctions in color are poorly discernable unless products are adjacent to one another.
- Color coding of drug classes can increase the chance of “intraclass” medication errors.
- Colors may fade when exposed to light.
- It is not always possible to exactly reproduce Pantone colors from batch to batch.
- Approximately 8% of men and fewer than 1% of women have some difficulty with color vision (colorblindness).
- Color coding can be error-prone if it is not applied consistently across the industry, or within a single manufacturer’s product line.
- Physicians and other health professionals may be unable to remember large or multiple-color coding systems.
- Color coding may offer a false sense of security and, in some instances, result in failure of the physician or other health professional to “read the label.”

COLOR CODING OF RESPIRATORY INHALERS

The coloring of outpatient SABA inhalers as blue and ICS as brown/red/orange in the United Kingdom and Canada is an informal convention that has been an accepted practice for several decades. No regulations have been issued by the United Kingdom Medicines and Healthcare Products Regulatory Agency, the European Medicines Agency, or Health Canada, and no formal agreement exists for manufacturers, regarding a color convention for respiratory inhalers. As a general principle, the three health agencies recommend against color coding.\textsuperscript{9,13,14} The European Medicines Agency has stated that "there can be no substitute for carefully reading the label before any medicine is taken."\textsuperscript{15} Color of inhalers is not addressed in guidelines for the management of asthma.\textsuperscript{16,17}

With the increasing diversity of inhaler devices, including combination products, entering the market in the United Kingdom and Canada, color coding is becoming more complex and inconsistent. The recent Health Canada approval of a long-acting $\beta_2$-adrenergic agonist (LABA) and ICS combination inhaler in the color blue\textsuperscript{18} has raised concerns.\textsuperscript{19} The existence of a generic salbutamol (a SABA) inhaler in brown in the United Kingdom adds confusion to the color coding convention.\textsuperscript{15} Manufacturers have been called on to consider universal concepts such as color coded dots or bands that correspond to different types of medications.\textsuperscript{20} However, the aforementioned disadvantages of color coding pharmaceutical products such as colorblindness and limited color availability persist and no formal action has been taken to ensure universal concepts.\textsuperscript{21}

Color Coding Respiratory Inhalers and Patient Adherence

A small survey of health care professionals in the United Kingdom found that the existing color convention for inhalers appears to be helpful in aiding communication between health care professionals and patients and can be helpful for reinforcing the different roles of inhalers and aiding in medication adherence.\textsuperscript{13} However, it should be noted that this communication between patients and physicians regarding inhaler color in the United Kingdom is likely aided by the color convention that has existed and been known for decades. A parallel situation of familiarity with a color convention does not exist for patients in the United States. The authors of the survey also noted a lack of studies regarding color-standardization in general and specific issues surrounding color coding such as color blindness.
Poor adherence to maintenance therapy is common among asthma patients and a complex challenge to overcome. Individualized action plans developed in a collaborative fashion between asthma patients and their physicians that focus on self-management are typically employed to promote adherence and appropriate clinical use of different inhalers. Inhaler color was of little importance in action plan discussions; emphasis was placed on when to use medications, skills training for use of inhalers, and education for asthma symptom management.

CONCLUSION

Although looked to for simplicity, limited evidence exists that color coding systems reduce medication errors in outpatients. Disadvantages of using color coding systems have been cited and experts either oppose color coding or recommend caution in its application. The FDA, Health Canada, and health agencies in the United Kingdom emphasize the best course of action before administration of any medication is to read the label. Even though the health agencies of United Kingdom and Canada recommend against color coding, an informal respiratory inhaler color coding convention exists in these countries. However, because of continued development of new products, including combinations, this color coding convention is becoming inconsistent and more complex. Experts evaluating the adherence of patients using inhalers have suggested that individualized counseling with personalized action plans and inhaler skills training are the best approach for improving adherence. With the lack of evidence to support a color coding scheme for outpatient respiratory inhalers, there is no justification for urging manufacturers to change inhaler colors, the potential cost associated with such a change which may be passed along to patients, and disruption to the current market of familiar inhaler products.

RECOMMENDATION

The Council on Science and Public Health recommends that the following statement be adopted in lieu of Resolution 906-I-16, “Universal Color Scheme for Respiratory Inhalers,” and the remainder of the report be filed:

Our American Medical Association supports research into mechanisms to improve patient understanding of their respiratory inhaler medications with the aim of improving safety and reducing unintentional medication errors, such as inhaler skills training and individualized action plans. (New HOD Policy)

Fiscal Note: Less than $500
REFERENCES

EXECUTIVE SUMMARY

**Background.** This report responds to Policy D-370.984 by reviewing current organ donation statistics, attitudes about donation, the disproportion between those needing a transplant and the organs available, factors influencing the decision to designate oneself as a donor, and educational interventions targeted to segments of the population with historically low rates of organ donation.

**Methods.** Literature searches were conducted in the PubMed database for English-language articles published between 2007 and 2017 using the search term “organ donation,” with the terms “minority,” “religion,” “education,” and “barriers.” A Google search was conducted using the same search terms. Additional articles were identified by manual review of the references cited in identified publications. The Health Resources and Services Administration (HRSA) Organ Donation and Transplantation and Organ Procurement and Transplantation Network websites, and the United Network for Organ Sharing website also were consulted.

**Results.** More than 33,000 transplants were performed in 2016, with kidney and liver transplants making up the majority. Most adults in the United States report supporting organ donation, yet only about half are registered as organ donors. Small but significant differences in support for organ donation and registration as an organ donor exist among certain racial and ethnic groups. Factors influencing support for organ donation are relational ties, religious and cultural beliefs, family influence, beliefs about body integrity after death, prior experience with the health care system, and knowledge about organ donation. Several educational programs addressing these factors and targeted to populations with low organ donation rates have been conducted in community and church settings, and have been variably successful in improving knowledge and positive perceptions about organ donation and intent to donate.

**Conclusion.** Although the number of organ donors and transplants has grown over the last two decades, the need for donated organs still far exceeds the number available for transplantation. This disparity is especially true for certain racial and ethnic minorities that make up a larger proportion of the transplant waiting list compared to their relative proportion among organ donors. Educational programs that address identified factors influencing attitudes toward organ donation and targeted to populations with historically low organ donation rates have been developed to improve donation. Those that have been successful should be continued and expanded to improve organ donation rates among populations most in need. In addition to targeted educational programs, successful non-targeted educational programs and other approaches should be continued as well.
REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2-I-17

Subject: Targeted Education to Increase Organ Donation

Presented by: Robert Gilchick, MD, MPH, Chair

Referred to: Reference Committee K (L. Samuel Wann, MD, Chair)

INTRODUCTION

Policy D-370.984, “Targeted Education to Increase Organ Donation,” asked:

That our American Medical Association study potential educational efforts on the issue of organ donation tailored to demographic groups with low organ donation rates.

This report responds to Policy D-370.984 by reviewing current organ donation statistics, attitudes about donation, disproportion between those needing a transplant and the organs available, factors influencing the decision to designate oneself as a donor, and educational interventions targeted to segments of the population with historically low rates of organ donation. Other factors affecting organ donation rates, including mandated choice and presumed consent for donation of cadaver organs, as well as novel models for living donation, have been discussed in Board of Trustees Reports 13-A-15 and 15-A-12.¹,²

METHODS

Literature searches were conducted in the PubMed database for English-language articles published between 2007 and 2017 using the search term “organ donation,” with the terms “minority,” “religion,” “education,” and “barriers.” A Google search was conducted using the same search terms. Additional articles were identified by manual review of the references cited in identified publications. The Health Resources and Services Administration Organ Donation and Transplantation and Organ Procurement and Transplantation Network websites and the United Network for Organ Sharing website also were consulted.

ORGAN DONATION STATISTICS AND ATTITUDES

Donated organs and tissues for transplantation are most often obtained from deceased donors, referred to as deceased organ donation. Deceased organ donors can donate kidneys, liver, lungs, heart, pancreas, and intestines. In addition to these organs, tissues such as heart valves, skin, bone, and tendons; corneas; and face and hands can be donated after death. Approximately 90% of organ donations are from deceased donors; the remaining donations are from living donors. Organs donated by living donors include one of two kidneys, one of two lobes of the liver, a lung or part of the lung, part of the pancreas, and part of the intestines. Tissues donated by living donors include skin, bone, bone marrow cells and umbilical cord blood cells, amnion (donated after childbirth), and blood. More than 33,000 transplants were performed in 2016. Kidney and liver transplants made up the vast majority of organs transplanted (approximately 58 and 23 percent, respectively).
Less common transplants were heart (9 percent), lung (7 percent), kidney and pancreas (2 percent), pancreas (0.7 percent), intestine (0.5 percent), and heart and lung (0.05 percent).4

Organ and tissue donation in the United States is voluntary. Individuals wishing to donate their organs after death “opt in” by documenting their desire. Deceased organ donation registration is a state process; individuals can sign up online with the state registry or through a state’s Department of Motor Vehicles. When the person’s preferences are not documented or known, the next of kin may decide to allow organs to be harvested for transplantation after death.3 More than 130 million adults in the United States (approximately 54% of the population) are registered as organ and tissue donors.4

Living organ donation is not administered through state or other government programs. Rather, it most often occurs in the form of directed donation, in which the donor names a specific person to receive the organ or tissue, usually a biological relative or a biologically unrelated person with a personal or social connection (spouse, significant other, friend, or acquaintance).7 In non-directed donation, the living organ donor does not name a recipient. Those wishing to be non-directed donors can do so by contacting a designated Organ Procurement and Transplant Network (OPTN) transplant center, or by contacting the United Network for Organ Sharing (UNOS).7

A 2012 survey of a nationally representative sample of US adults, administered by the Health Resources and Services Administration (HRSA), examined organ donation attitudes and behaviors. More than 95 percent of respondents supported or strongly supported the donation of organs for transplantation.8 Small but significant differences in support exist among racial and ethnic groups. Approximately 95 percent of those categorizing themselves as White, Asian/Pacific Islander, or Hispanic support or strongly support donation, while approximately 92 percent of Native Americans and 87 percent of African Americans support or strongly support donation.8 Despite strong support for organ donation, the survey indicated that fewer people took steps to register as organ donors; only 60 percent of respondents with a driver’s license reported that they had granted permission for organ donation on their driver’s license.8 Racial and ethnic differences were apparent on this measure as well; 65 percent of White, 56 percent of Asian/Pacific Islander, 47 percent of Native American, 44 percent of Hispanic, and 39 percent of African-American respondents with a driver’s license reported that they had granted permission for organ donation on their license.8

ORGAN DONATION NEEDS

Although the number of both donors and transplants has been growing slowly over the last two decades, the need for donated organs far exceeds the number available for transplantation. Nearly 120,000 people are on the national transplant waiting list, with the vast majority (81 percent) waiting for a kidney.4 Only about three in 1,000 registered donors actually become donors after death. This is due to a number of criteria that must be met for a donor organ to be appropriate for an intended recipient (the “matching” process). These include blood and human leukocyte antigen (HLA) type, body size, severity of the recipient’s medical condition, severity of donor’s pre-death medical condition, length of time on the waiting list, distance between the donor’s and recipient’s hospitals, and the availability of the recipient.9

The proportion of racial and ethnic minority patients on the waiting list is higher than the corresponding proportion of racial and ethnic minorities who are donors.4 For example, African Americans make up nearly 30 percent of patients on the waiting list, but only approximately 16 percent of donors are African American.4 Hispanics and Asians make up nearly 20 and 8 percent, respectively, of patients on the waiting list, but only approximately 14 and 3 percent of donors are
Hispanics and Asians, respectively.\(^4\) This disparate representation on the transplant waiting list exists partially because minority groups, specifically African Americans, are disproportionately impacted by chronic conditions such as diabetes, heart disease, and hypertension, which often are managed with transplants.\(^{10,11,12}\) Additionally, African Americans have more HLA polymorphisms and enhanced alloreactivity, making the chance of finding a matching donor, especially among a pool of donors that includes proportionally fewer African Americans, particularly difficult.\(^{10,12,13}\)

### FACTORS INFLUENCING ORGAN DONATION

Irving et al.\(^{14}\) conducted a systematic review of studies that characterized factors influencing attitudes toward deceased and living organ donation, and categorized the factors into several broad themes:

- **Relational ties:** The needs of family members or friends appear to be more influential in the decision to become a donor than those of strangers. Many study participants were willing to donate an organ to a family member or friend even if they were not willing to donate to someone they did not know.

- **Religious beliefs:** While some believe that organ donation aligns with the altruistic tenets of their religion, others believe that donation is not consistent with their religion. For example, some Islamic study participants interpret the Qur’an and traditional Islamic literature as forbidding organ donation. Others believe that transplantation, and therefore the facilitation of transplantation through organ donation, is “playing God.” The most common religious objection to organ donation was the need to maintain body wholeness to enter the next life.

- **Cultural beliefs:** Cultural beliefs concerning health care and death and dying, often based on superstition, are associated with lack of support for organ donation. For example, study participants cited the belief among some cultures that discussing death could lead to one’s own death. Others believe that death is a private matter, that ancestral approval is needed before organ donation, and that grieving rituals are disrupted by organ donation.

- **Family influence:** Family members’ beliefs about organ donation often influence individual beliefs. Study participants with one or both parents who object to organ donation expressed reluctance to be donors themselves, and some participants believed that they should seek permission from family members if they wanted to be donors. Other participants believed that by designating themselves as organ donors, they were sparing their family members difficult decisions after their death.

- **Body integrity:** Apart from religion, body integrity after death appears to influence support for donation. Participants worried that family members would be traumatized about the thought of their bodies being “cut up,” and that organ donation would preclude an open coffin at their funeral.

- **Interaction with the health care system:** A distrust of the organ donation system and process, often based on negative experiences with the health care system, reduce support for organ donation. Participants questioned the concept of “brain death,” and were suspicious of health care providers making such a designation. Some believed that organ donors would not receive proper care since health care personnel would only be interested in harvesting their organs, or that donor bodies would not be treated with dignity and
respect. Opinions based on previous experience or interactions with the health care system were more prevalent among study participants belonging to minority groups that have historically experienced a sense of marginalization from the health care system.

- Knowledge about the organ donation process: A lack of knowledge about the organ donation process is a barrier to donation. Study participants expressed the need for more information before they could commit to donation, and a lack of awareness about where such information could be obtained.

Across a number of studies assessing characteristics of those willing to donate, individuals who are younger, are female, have higher educational levels and/or socioeconomic status, and have higher knowledge about organ donation are generally more likely to have positive attitudes toward donation and are more willing to donate. The HRSA organ donation attitudes and behaviors survey found that the following attitudes were predictors of designating oneself as an organ donor:
   - placing low importance on body wholeness after death, family support for organ donation, being receptive to receiving a transplant as a life-saving measure, an understanding that many people die while on the transplant waiting list, and not believing the notion that physicians would be less likely to save the life of a person who is a donor.

Some factors influencing support for organ donation are more pronounced in certain racial or ethnic groups than in others. For example, interviews with African Americans found the following as predominant barriers: religious beliefs and misperceptions, distrust of the medical establishment, fear of premature declaration of death if a donor card has been signed, and a preference among African American donors for assurance that the organs will be given preferentially to African American recipients. In Native Americans, the importance of traditional religious beliefs, including the need to be buried with an intact body, is a barrier to deceased organ donation. Among Hispanics, greater concern over body disfigurement and greater doubt that physicians do all they can to preserve life before pursuing organ donation exist compared to non-Hispanic whites.

It is unclear that religion itself is a consistent barrier to organ donation. The role of religion in support for organ donation is often confounded by community and cultural norms. In international studies, Buddhists have reported objection to deceased organ donation based on the religious belief that a person's spirit remains in the body as long as the heart is still beating, even though brain death has occurred. This is despite a central Buddhist tenet that honors persons who donate their organs to save a life. Studies of Muslims have indicated that religious beliefs are a barrier to organ donation, and in the United States, Muslims who demonstrate negative aspects of religious coping (a psychological state in which individuals express an insecure relationship with God and an ominous view of the world) are more likely to hold negative attitudes toward organ donation. However, other measures of Muslim religiosity are not correlated with organ donation attitude, and many Muslims in the United States believe that donation is justified. Among Christians, non-Catholic Christians are more likely to report willingness to be organ donors than are Catholic Christians.

TARGETED EDUCATIONAL INTERVENTIONS TO INCREASE DONATION

Given the significant need to increase the number of organs available for donation, educational interventions are needed to improve willingness to donate. Ideal interventions include those that address perceptions that influence the decision to donate and target populations most likely to hold such perceptions. A systematic review of interventions to improve organ donor registration among minorities found that educational interventions alone or combined with mass media...
approaches (as opposed to mass media alone) were most effective.\textsuperscript{25} Those that included strong interpersonal components, were delivered by members of the local community in familiar environments, and included immediate opportunities to register were important for improving outcomes.\textsuperscript{25} Others have emphasized culturally appropriate strategies to engage minority groups, and comprehensive information about organ donation that can be easily obtained.\textsuperscript{14} A recent study examining factors that may facilitate the willingness of African Americans to become organ donors determined that improving knowledge about organ donation, particularly with regard to donor involvement and donation-related risks, may be successful in increasing organ donation.\textsuperscript{26}

Examples of national, church-based, and community-based targeted educational interventions are summarized below. It is important to note that although some interventions appear to have been successful in improving knowledge and attitudes about organ donation, discussion of organ donation with family members, and changing organ donor status, it is generally difficult to measure intervention success because of concurrent programs that directly or indirectly affect organ donation.\textsuperscript{27} For example, policies aimed at motorcycle helmet use, health system transformation, public health spending, smoking rates, and chronic disease affect the health of the donor pool, which in turn could affect the number of organs available for donation.\textsuperscript{27}

**Nationally Targeted Interventions**

The National Minority Organ Tissue Transplant Education Program (MOTTEP) was created in 1991 with a mission to decrease the number of ethnic minority Americans on transplant waiting lists.\textsuperscript{17,28,29,30} Fifteen national sites were funded to carry out community-based programs that centered on approaches including community participation and direction to target specific community differences; face-to-face presentations, especially to smaller audiences to foster discussion; collaboration and partnerships with religious, social, and civic organizations; media promotion of MOTTEP’s message; dissemination of culturally sensitive and informative brochures, videos, public service announcements, and other information; and comprehensive evaluation to gauge effectiveness of the program.\textsuperscript{17,29,31} The number of organs recovered for transplantation from African Americans increased more than 3-fold between 1991 and 2016, with some suggesting the success is partially due to MOTTEP efforts.\textsuperscript{29,31,32}

**Church-Based Targeted Interventions**

Another educational program targeting African Americans, Project ACTS (About Choices in Transplantation and Sharing), was a self-administered donation education intervention developed with a focus on addressing religious barriers to donation and encouraging family discussion.\textsuperscript{33} The program consisted of materials distributed at churches that are taken home and reviewed individually. The materials included a video hosted by a gospel choir with excerpts from individual and family conversations about beliefs, attitudes, myths, misconceptions, and fears about organ donation/transplantation; an educational pamphlet; a donor card; a National Donor Sabbath pendant; and several additional items embossed with the project name and logo. Participants in the program were 1.6 times more likely to have discussed, or be in discussion, with family members about their organ donation wishes than those who had not participated in the program.\textsuperscript{33} A revised program, Project ACTS II, was designed to improve uptake by testing the intervention in individual and group settings.\textsuperscript{34} Participants in the revised program who viewed the video in a group setting had a significantly greater increase in positive attitudes toward donation and beliefs than those who were given the video to view at home.\textsuperscript{34} It is thought that the group dynamic provided an opportunity for active contemplation of donation-related beliefs, attitudes, and the act of registration, and engaged people in a way that could not be attained by reviewing materials individually.\textsuperscript{34}
A church-based intervention targeted to Hispanics entailed a 45-60 minute educational program, created specifically for religious organizations, administered to participants in four Catholic churches whose membership was predominantly Hispanic. The program, led by a local organ procurement organization and conducted in both English and Spanish, included factual information about the need for organ and tissue transplantation, how the organ donation and allocation process serves such a need, and discussion of religious misconceptions regarding organ donation. After the intervention, significant increases in organ donation knowledge and positive perceptions regarding organ donation were observed. However, no change in intent to donate was observed. Interestingly, both before and after the intervention, those whose families supported organ donation were more likely to indicate intent to donate than those whose families did not support donation. The study authors therefore suggest that education focused on family support is important in improving intent to donate.

Other church-based education programs have not been successful. A peer-led program at predominantly African American churches, in which a church member was trained to provide educational sessions within the church, included the viewing of a video and discussions about organ donation and the provision of brochures and flyers containing the web address of the donor registry. No statistically significant differences in organ donation attitudes or intent to donate were observed following the intervention. The study concluded that lack of pastoral support may have influenced outcomes, and that participants misinterpreted the consent form to be involved in the study as an affirmative indication that they wished to be organ donors.

Community-Based Targeted Interventions

A 2007-2012 community-based intervention targeting Hispanics resulted in an increase in consent for organ donation. Media messages were conveyed on television and radio, and culturally sensitive educational programs were held at high schools, churches, and medical clinics in four Southern California neighborhoods with a high percentage of Hispanic residents. Among those targeted by the intervention, the consent rate for organ donation increased significantly from 56 percent before the intervention to 83 percent after the intervention.

A different approach has been to use peer-to-peer techniques to deliver health education messages. This technique was employed in several Michigan hair salons, with hair stylists acting as lay health advisors to improve organ donation among their African-American clients. Stylists delivering the intervention were asked to discuss organ donation at least twice with their clients. Following the intervention, clients in the intervention group were 1.7 times more likely than those in the control group (in which general health topics, but not organ donation specifically, were discussed) to report positive donation status.

CURRENT AMA POLICY

The AMA has a number of policies related to improving organ donation. Regarding education, AMA policy supports “state of the art” educational materials for the medical community and the public that address the importance of organ donation and the need for organ donors, development of effective methods for meaningful exchange of information to educate the public about donating organs, implementation of UNOS recommendations for organ donation, and the provision of educational materials by states and local organ procurement organizations to attendees of driver education and safety classes. AMA policy also encourages research on methods for increasing the number of organ donors in the United States, including studies that evaluate the effectiveness of mandated choice and presumed consent models for increasing organ donation; studies evaluating the use of incentives,
including valuable considerations, to increase living and deceased organ donation rates (H-370.958); and pilot studies on promotional efforts that stimulate each adult to respond "yes" or "no" to the option of signing a donor card. Ethical Opinion 6.1.4, “Presumed Consent and Mandated Choice for Organs from Deceased Donors,” describes the ethical challenges of presumed consent and mandated choice models and emphasizes the need for education about organ donation.

CONCLUSIONS

Although the numbers of organ donors and transplants have grown over the last two decades, the need for donated organs still far exceeds the number available for transplantation. This disparity is especially true for certain racial and ethnic minorities that make up a larger proportion of the transplant waiting list compared to their relative proportion among organ donors. Educational programs that address identified factors influencing attitudes toward organ donation and targeted to populations with historically low organ donation rates have been developed to improve donation. Some have been successful at improving knowledge about organ donation, comfort in discussing organ donation wishes with family members, and intent to donate; however, it is difficult to determine the impact of the programs on donation because they do not occur in isolation from other factors that may influence organ donation rates.

Non-targeted educational approaches have had success as well. For example, an organ donation registration campaign in California consisting of intense public awareness using public service announcements; news conferences; and community outreach in federal buildings, universities, and libraries; combined with an online organ donor registration process at the Department of Motor Vehicles, improved consent for donation from 47.5 percent before the campaign to 51 percent after the campaign. And direct mail campaigns, in which information about organ donation and a request to join the state organ donor registry are mailed to residents, have been successful in prompting both young adults and older adults to join organ donation registries.

Additionally, other approaches to improving organ donation rates should be explored. A 2015 analysis examined a number of state policies on organ donation, including first-person consent laws, donor registries, dedicated revenue streams for donor recruitment activities, population education programs, paid leave for donation, and tax incentives, and found that only revenue policies to promote organ donation had any effect on organ donation and transplantation. These revenues can be used on funding for outreach campaigns and educational programs that incorporate elements that appear to be most successful in increasing intent to donate. Others have proposed that financial incentives in the form of a contribution to a donor’s retirement fund, an income tax credit, a tuition voucher, or a posthumous funeral benefit would be far more effective at increasing the donor pool than educational approaches.

The Council on Science and Public Health supports continued implementation of targeted educational programs that have shown promise in increasing intent to donate, and encourages further study of other approaches that may be successful.
RECOMMENDATIONS

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

1. That Policy H-370.959, “Methods to Increase the US Organ Donor Pool,” be amended by addition to read as follows:

   In order to encourage increased levels of organ donation in the United States, our American Medical Association: (1) supports studies that evaluate the effectiveness of mandated choice and presumed consent models for increasing organ donation; (2) urges development of effective methods for meaningful exchange of information to educate the public and support well-informed consent about donating organs, including educational programs that address identified factors influencing attitudes toward organ donation and targeted to populations with historically low organ donation rates; and (3) encourages continued study of ways to enhance the allocation of donated organs and tissues. (Modify Current HOD Policy)

2. That Policy D-370.984 be rescinded, having been accomplished through this report. (Rescind HOD Policy)

Fiscal note: Less than $1000
REFERENCES

24. Deedat S, Kenten C, Morgan M. What are effective approaches to increasing rates of organ donor
REPORT 3 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-17)
Neuropathic Pain as a Disease
Resolution 912-I-16
(Reference Committee K)

EXECUTIVE SUMMARY

Objective. This report considers whether neuropathic pain should be recognized as a distinct disease state.

Methods. English-language reports on studies using human subjects were selected from a MEDLINE search of the literature from 2005 to August 2017 using the search terms “neuropath*,” in combination with “pain,” and “pathophysiology,” “chronic,” and “pain as a disease.” A total of 103 articles were retrieved for analysis based on their ability to supply new information about the pathogenesis of chronic and neuropathic pain, as well as viewpoints on whether chronic (including neuropathic) pain can or should be considered as a disease in its own right. Medical dictionaries were consulted for definitions of disease and related terms.

Results. Understanding of the human pain experience has evolved over time. Although a detailed understanding of the neuroanatomy underlying the perception of noxious stimuli (nociception), exists, neuroimaging studies have identified several brain regions that are activated during the pain experience, dubbed the “pain matrix;” many of the same regions are also activated during various emotional and behavioral responses. Chronic pain is now recognized as an integrative sum of nociceptive input and factors related to cognition, mood, and context, as well as individual biologic, psychologic and social factors and various co-morbidities. Many “diseases” are accompanied by persistent pain, and chronic pain itself has been described by some as a disease. With respect to neuropathic pain, many different types of neural lesions and systemic diseases trigger neuropathic pain symptoms, which include various positive, negative, and evoked symptoms. Much of the thinking about chronic pain as a disease has been driven by the results of neuroimaging studies. Neuropathic pain also is characterized by adaptive cellular and functional changes which appear to persist after healing of the original injury. Based on neuroimaging, cross sectional studies of structural and functional changes accompanying chronic pain, including neuropathic pain, support clear differences compared with both normal conditions and the presence of acute nociceptive pain. It remains unclear what the cause and effect relationships might be, or whether such brain alterations should be viewed primarily as an adaptive response to continuing nociceptive input.

Conclusion. Evaluating neuropathic pain as a distinct disease state would be best deliberated by a group of multi-specialty experts involved in the evaluation and treatment of pain who could more deeply focus on the topic and consider all of its ramifications. At the 2016 Interim Meeting the House adopted a resolution directing the American Medical Association (AMA) to convene a Federation-based pain care task force (Policy D-160.922). This task force is in the process of being formed, and the Council believes that it is a more appropriate body to address this issue in a comprehensive manner.
Resolution 912-I-16, “Neuropathic Pain as a Disease,” introduced by the American Academy of Pain Medicine at the 2016 Interim Meeting and referred to the Board of Trustees, asked:

That our American Medical Association recognize neuropathic pain as a disease state with multiple pathophysiological aspects requiring a range of interventions to advance neuropathic pain treatment and prevention.

METHODS

English-language reports on studies using human subjects were selected from a MEDLINE search of the literature from 2005 to August 2017 using the search terms “neuropath*,” in combination with “pain,” and “pathophysiology,” “chronic,” and “pain as a disease.” A total of 103 articles were retrieved for analysis based on their ability to supply new information about the pathogenesis of chronic and neuropathic pain, as well as viewpoints on whether chronic (including neuropathic) pain can or should be considered as a disease in its own right. Medical dictionaries were consulted for definitions of disease and related terms.

BACKGROUND

The Council previously examined the issue of neuropathic pain on two occasions. In 2005, the Council reviewed the neurobiology of nociceptive and neuropathic pain, and the definition, classification, common causes, diagnostic approach, and pharmacologic management of neuropathic pain.1 In 2010, the Council reviewed more recent findings about how neural damage, which is the signature precipitating event for the development of neuropathic pain, provokes multiple responses in nociceptive pathways that generate and amplify pain.2 Such responses include peripheral and central sensitization, ectopic activity in pain carrying fibers, neuronal cell death, disinhibition, altered gene expression, neuron sprouting, neuronal plasticity and modified neural connectivity.2 Some discussion was devoted to whether such changes, which can eventually persist in the absence of ongoing noxious stimuli, should be considered maladaptive and warrant consideration as a disease. The Council did not specifically endorse that viewpoint, concluding in part, that the clinical value of viewing chronic or neuropathic pain as a disease was not established. This report responds to the specific request that our AMA, through Council evaluation and deliberation by the House of Delegates, recognize neuropathic pain as a disease state. It is already established that neuropathic pain is characterized by “multiple pathophysiologic aspects” and requires a treatment approach that differs from that applied to chronic nociceptive and inflammatory pain.
RELEVANT DEFINITIONS

Pain
Pain is “an unpleasant sensory and emotional experience associated with actual or potential tissue
damage or described in terms of such damage.” This definition acknowledges that pain is a
conscious experience involving interpretation of (painful) sensory input that is influenced by
emotional, pathological, and cognitive factors, as well as previous pain experiences.

Nociceptive Pain
Nociceptive pain is caused by tissue injury generating pain through the primary somatosensory
nervous system via a process involving activation of peripheral nociceptors, transduction,
transmission, modulation and perception of noxious stimuli. Nociceptive pain can be acute,
subacute or chronic, may be complicated by inflammation, and may be visceral or referred in
origin.

Chronic Pain
Chronic pain has been variously defined. The definition used by the Centers for Disease Control
and Prevention in developing its guideline on the use of opioids in chronic noncancer pain is based
on the International Association for the Study of Pain (IASP) definition:
“Ongoing or recurrent pain, lasting beyond the usual course of acute illness or injury healing,
more than 3 to 6 months, and which adversely affects the individual’s well-being”

Neuropathic Pain
Neuropathic pain was re-defined by the IASP in 2012 as “pain initiated or caused by a lesion or
disease of the somatosensory system.” The basis for this definition is that “neuropathic pain is not
a single disease, but a syndrome caused by a range of different diseases and lesions, which
manifests as an array of symptoms and signs.”

Disease
- An interruption, cessation, or disorder of body function, system, or organ OR a morbid
entity characterized usually by at least two of these criteria: recognized etiologic agent(s),
identifiable group of signs and symptoms, or consistent anatomic alterations.
- Any deviation from or interruption of the normal structure or function of any body part,
organ, or system that is manifested by a characteristic set of symptoms and signs whose
etiology, pathology, and prognosis may be known or unknown.

Syndrome
The aggregate of symptoms and signs associated with any morbid process, and constituting
together the picture of the disease.

Disorder
An illness that disrupts normal physical or mental functions.

EVOLUTION OF PAIN THEORY

Initial investigation and understanding of pain focused on describing the specific somatosensory
pathways involved in pain processing. Nociception is the perception of noxious stimuli and
represents an alarm signal mediated by specialized primary afferent (sensory) neurons that respond
to sufficiently intense thermal, mechanical, or chemical stimuli, transduce these stimuli into
electrical activity, and transmit signals via well-defined pathways in the central nervous system.
Cell bodies of the primary afferent neurons are located in dorsal root ganglia and the spinal sensory
nucleus of cranial nerve V; bifurcated axonal processes are distributed to the periphery for
detection, and to the spinal cord to transmit information centrally. Aδ fibers (thinly myelinated)
carry a well-localized “first” pain of sharp, pricking quality. C fibers (unmyelinated) carry a poorly
localized “second” pain of dull and persistent or burning quality. Muscle and deep tissue nociceptor
stimulation produce aching or cramping type pain. There are several sub-populations of primary
afferents that differ in their axon diameter, response to stimuli, neurophysiologic and
neurochemical characteristics and targets in the dorsal horn of the spinal cord. When local
inflammation ensues, certain features of the nociceptive response are modified and magnified to
aid healing and repair.

In the spinal cord, peripheral pain-carrying primary afferent terminals synapse on (second order)
neurons within the superficial lamina of the dorsal horn, which ascends to form the spinothalamic
tract and spinoreticular system. The former transmits information about acute pain (location,
intensity, quality) through the thalamus to the somatosensory cortex and the latter is involved with
autonomic and affective reactions to pain. The dorsal horn is not a simple relay station but is
subject to “gating” by local interneurons with inhibitory and excitatory influences, as well as
descending influences from the midbrain and higher centers.

Secondary spinal projection neurons transmit nociceptive information to brainstem regions,
including the rostral ventral medulla and periaqueductal gray (PAG); this information is further
modulated in the brainstem, relayed to the thalamus, and then transmitted to the cortex where it is
interpreted as pain. Several cortical regions are involved in pain processing, including the primary
somatosensory cortex, secondary somatosensory cortex, insular cortex, prefrontal cortex, and
motor cortex.

The Pain Matrix

Although a detailed understanding of the neuroanatomy of nociception exists, neuroimaging
studies have identified several brain regions that are activated during the “pain experience.” This
pattern of neural activation has been posited to represent an array of interrelated brain regions
integral to human pain perception and response or colloquially representing the “neurosignature of
pain.” An extensive neural network (dubbed the “pain matrix”) is accessed during the
processing of nociceptive input including the primary and secondary somatosensory, insular,
anterior cingulate, and prefrontal cortices and the thalamus; subcortical areas (e.g., brain stem,
PAG, hypothalamus, amygdala, hippocampus, and even the cerebellum) also are involved in the
pain experience. Thus, modulation of the primary nociceptive stimulus occurs within the spinal
cord where noxious stimuli are just part of the overall sensory input, in response to descending
neuronal influences, and at numerous supraspinal levels affecting the discriminative, emotional,
and cognitive aspects of pain.

Neuroimaging studies have shown that many brain regions activated by nociceptive stimuli also are
activated during various emotional and behavioral responses, and that non-nociceptive events or
inputs (e.g., loss of a loved one, social exclusion) can produce pain-like experiences. These
types of findings have informed a conceptual three-tiered hierarchical model of the human pain
experience based on nociception (1st tier), conscious perception subject to cognitive and attentional
modulation and the triggering of somatic reactions (perceptive-attentional, 2nd tier), and
consideration of how individual factors and characteristics (including psychological factors and
emotional context) influence pain and the memory of that experience (reappraisal-emotional, 3rd
tier). Brains regions involved in the second and thirds tiers can either inhibit or facilitate
nociception in a descending fashion.
**The Biopsychosocial Model of Chronic Pain**

Pain is an individual and subjective experience, recognized as an integrative sum of nociceptive input and factors related to cognition, mood, and context, as well as individual variables such as genetics and sex. Chronic pain and patient outcomes are influenced by individual biologic, psychologic and social factors and various common comorbidities (Figure 1). Brain regions involved in the pain matrix are involved in many other sensory, motor, cognitive, and emotional functions and a reciprocal relationship exists between chronic pain and mental health disorders. Neural pathways that involve pain, depression and anxiety overlap and likely have important biological interactions that are not well understood. Chronic pain induces disturbances in mood (reactive depression or anxiety), impaired coping (often with catastrophization), and other processes which can worsen pain and pain-related distress and lead to fear-avoidance behaviors. Pain patients also have much higher premorbid or comorbid psychosocial concerns, mental health disorders and cognitive distortions that influence the pain experience and drive pain-related distress. Individuals who observe other people’s suffering often experience a subjective enhancement of their own pain suffering. Thus, the pain experience is influenced by various cognitive, emotional, and environmental factors affecting brain function.

**IS CHRONIC (OR NEUROPATHIC) PAIN A DISEASE?**

Many “diseases” are accompanied by persistent pain including cancer, human immunodeficiency virus infection, osteoarthritis/rheumatoid arthritis, lower back injury, headache, degenerative spine disease, fibromyalgia, diabetes, post-herpetic neuralgia, etc. However, when considering whether neuropathic pain is a disease, it is important to note that the question of whether chronic pain should be considered a disease is not a new concept.

In 2001, the IASP and the European Federation of IASP Chapters adopted the following declaration:

“Pain is a major healthcare problem worldwide. Although acute pain may reasonably be considered a symptom of disease or injury, chronic and recurrent pain is a specific healthcare problem, a disease in its own right.”

The landmark 2011 report by the Institute of Medicine on Relieving Pain in America concluded that:

Chronic pain can be a disease in itself. Chronic pain has a distinct pathology, causing changes throughout the nervous system that often worsen over time. It has significant psychological and cognitive correlates and can constitute a serious, separate disease entity.

In 2016 Vardeh et al noted:

The past few decades have witnessed a huge leap forward in our understanding of the mechanistic underpinnings of pain, in normal states where it helps protect from injury, and also in pathological states where pain evolves from a symptom reflecting tissue injury to become the disease itself.

**Neuropathic Pain**

With respect to neuropathic pain, many different types of neural lesions and systemic diseases trigger neuropathic pain symptoms (e.g., diabetes, post-herpetic neuralgia, radiculopathies, stroke,
spinal cord injury, chemotherapy, certain surgeries, alcohol misuse, vitamin deficiencies, heavy metal toxicity, and many other causes and triggers). Signs and symptoms characteristic of neuropathic pain include spontaneous “positive” (gain of function) signs (e.g., paresthesias, burning, shooting or shock-like pains), “negative” (loss of function) signs (e.g., numbness, weakness, hypoalgesia, decreased tendon reflexes) and certain stimulus-dependent or evoked signs (e.g., allodynia, hyperalgesia) (Figure 2). Diseases causing neuropathic pain vary substantially in terms of anatomical location and cause; depending on the cause, individual patients exhibit similar clinical characteristics, but not all symptoms that are commonly associated with neuropathic pain. Two prominent neuropathic pain symptoms across causes are alldynia (pain induced by normally innocuous stimuli) and hyperalgesia (increased pain in response to noxious stimuli) (see below).

Debate on Chronic Pain as a Disease

The field of pain medicine, the Institute of Medicine and some clinicians and researchers have proposed that chronic pain should be considered a disease; others continue to see pain primarily as a symptom of disease. Much of the thinking about chronic pain as a disease has been driven by neuroimaging studies, and structural/functional changes observed in animal models of chronic pain and/or neural injury. It has been proposed that because some unique changes accompany neural injury, chronic pain with a neuropathic component should be considered in a distinct fashion.

Neuroimaging. An extensive literature base exists on using various brain imaging techniques in patients with chronic pain, including neuropathic pain; most studies have been cross-sectional. A comprehensive review is beyond the scope of this report. A critical review of more than 100 brain neuroimaging reports identified neural correlates of chronic pain associated with various diseases (i.e., osteoarthritis, irritable bowel syndrome, back pain, fibromyalgia) and demonstrated distinctions from images associated with acute nociceptive pain. Patients suffering from chronic pain also exhibit dysfunction in descending inhibition of pain, less gray matter in the thalamus and prefrontal cortex with more gray matter loss in patients with neuropathic components; differences in various measures of brain neurochemistry also have been demonstrated. Subsequent studies extended these findings to other chronic pain conditions (pelvic pain, complex regional pain syndrome, diabetic peripheral neuropathy, phantom limb pain) demonstrating changes in gray matter density in multiple cortical regions, as well as the amygdala and hippocampus. What remains unresolved is to what extent altered structure, function and neurochemistry represents a “disease” or are simply neuroplastic adaptive processes in response to ongoing nociceptive input, or reflect the consequences of pain, common co-morbid conditions, medications, or altered lifestyles in patients with chronic pain.

Cellular and Functional Changes. Adaptive and persistent cellular and functional modifications also have been used to support the concept that neuropathic pain, in particular, is a chronic disease. As described in the previous Council report, neural injury provokes a host of neuroplastic and neuroimmune responses which become drivers of neuropathic pain, some of which also are common to persistent nociceptive/inflammatory pain. These include:

- peripheral sensitization of nociceptors related to altered trafficking of ion channels. Peripheral sensitization decreases the threshold for activation and augments normally painful stimuli (primary hyperalgesia) and triggers the development of spontaneous (ectopic) activity in primary afferent neurons;
- central sensitization, characterized by increased spontaneous activity, expansion of receptive fields, and a decreased threshold to primary afferent inputs into the dorsal horn. This ultimately enhances the function of neurons and circuits in nociceptive pathways via
increased membrane excitability, increased synaptic efficacy, and reduced inhibition. It manifests as mechanical allodynia and secondary hyperalgesia;

- changes in the phenotype of low threshold sensory fibers (Aβ) that are normally activated by touch, pressure, and vibration, to one whereby they can generate sensations of pain or tenderness;
- a pathological triad of reciprocal interactions among neurons, immune cells, and glial cells with glia activation and release of proinflammatory mediators that contributes to both peripheral and central sensitization; and
- disinhibition resulting from an imbalance of excitatory and inhibitory influences at the spinal cord level, and descending facilitation from the brain stem and higher centers.

DISCUSSION AND COMMENT

Recognition of chronic pain as a disease may lead to increases in resources, education, and priority, but considerable attention has already been devoted to the burden of chronic pain in the United States, and a National Pain Strategy has been developed.47

A disease, by definition, requires a set of “characteristic signs and symptoms.” Chronic pain is:

- complex, affecting individuals physically, mentally, socially and spiritually. This results in a common symptomatic and functional spectrum of physical, cognitive, psychological and behavioral effects. Decreased physical functioning coupled with little hope for effective treatment often results in a downward spiral of depression, distress, anxiety, and sleep problems, which lead to impaired social functioning and family relationship that all increase perceived pain.48

Some of these consequences may be explained by common neural substrates or reciprocal interactions and may not be considered unique to chronic pain because they can accompany any chronic condition that causes substantial distress.

With neural injury or repetitive nociceptive stimuli, remodeling of the nervous system and alteration in gene expression occurs. Such changes reflect neuroplasticity that impacts pain in the peripheral and central nervous system, leading to increased excitability within pain circuits and generating peripheral and central sensitization, which underlie the phenomena of hyperalgesia, allodynia, and the spread of pain to adjacent uninjured regions (secondary hyperalgesia). Based on neuroimaging research, cross sectional studies of structural and functional changes accompanying chronic pain, including neuropathic pain, support clear differences compared with both normal conditions and the presence of acute nociceptive pain, but it remains unclear what the cause and effect relationships might be, or whether such brain alterations should be viewed primarily as an adaptive response to continuing nociceptive input. Do these phenomena fulfill the requirement for the presence of “characteristic signs and symptoms?” Does it make sense to consider an altered pain response as a symptom that can logically define pain as a disease?

With respect to pain management and relieving the burden of suffering among patients with chronic pain, it would seem that wider adoption of the biopsychosocial model of pain management should be the most important goal, with attention to reducing pain, restoring function, cultivating well-being and improving quality of life. This requires identifying and addressing psychosocial contributors and emphasizing active over passive modalities. For neuropathic pain, diagnostic and management approaches are different; preferred initial pharmacological interventions are antiepileptic and antidepressant drugs. Several interventional approaches are available but psychobehavioral approaches can be more challenging in patients with neural injury.2
CONCLUSION

The topic of neuropathic pain as disease would be best deliberated by a multi-specialty group of experts involved in the evaluation and treatment of pain that could more deeply focus on the topic and consider all of its ramifications. At the 2016 Interim Meeting the House of Delegates adopted a resolution directing the AMA to convene a Federation-based pain care task force (Policy D-160.922). This task force is in the process of being formed and the Council believes that it is a more appropriate body to address this issue in a comprehensive manner.

RECOMMENDATION

The Council on Science and Public Health recommends that the following statement be adopted in lieu of Resolution 912-I-16 and the remainder of this report be filed:

That the Federation Task Force on Pain Care evaluate the relative merits of declaring neuropathic pain as a distinct disease state, and provide a recommendation to the Council on Science and Public Health. (Directive to Take Action)

Fiscal Note: Less than $500
REFERENCES


Figure 1. Biopsychosocial Context of Pain

- Physiologic Stimulus
  - Neuropathic/Nociceptive

- Individual Biopsychosocial Context
  - Life Experiences
  - Environmental Stressors
  - Work History
  - Family/Friends
  - Dynamics & Support
  - Culture
  - Self-Efficacy
  - Coping
  - Acceptance
  - Suffering

- Experience of Pain
  - Quality of Life
  - Health Status
  - Conditioning
  - Functioning
  - Cognition
  - Mood
  - Substance Use
  - Sleep
  - Biogenetics
Figure 2. Signs and Symptoms Characteristic of Neuropathic Pain

- **Neuropathic Pain**
  - **Positive Signs**
    - “Paresthesias (“Tingling”, “Pins and Needles)
    - “Burning” or “Hot”
  - **Stimulus-dependent Evoked**
    - Allodynia
    - Hyperalgesia
    - Hyperpathia
  - **Negative Signs**
    - Numbness
    - Weakness
    - Hypoesthesia
    - Hypoalgesia
    - ↓Tendon reflexes
INTRODUCTION

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 informational 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 August 2017, 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) 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.

BACKGROUND

The Council has issued seven reports on drug shortages. The findings and conclusions of the first five reports are summarized in CSAPH Report 2-I-15. The remainder of this report will update information on drug shortages since the 2016 report was developed.

CURRENT TRENDS IN DRUG SHORTAGES

The two primary data sources for information on drug shortages in the United States continue to be the Drug Shortage Resource Center maintained by ASHP in cooperation with the University of Utah Drug Information Service and the Drug Shortage Program at the FDA. Table 1 summarizes how the ASHP’s and FDA’s information and statistics on drug shortages are developed. The ASHP defines a drug shortage as “a supply issue that affects how the pharmacy prepares or dispenses a drug product or influences patient care when prescribers must use an alternative agent.” The FDA defines shortages as “a period of time when the demand or projected demand for a medically necessary drug in the United States exceeds its supply.” Medically necessary drugs are

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defined by FDA as “any drug product used to diagnose, treat, or prevent a serious disease or medical condition for which there is no other drug that is judged to be an appropriate substitute or there is an inadequate supply of an acceptable alternative.”

Because their criteria differ (the main distinction being the FDA’s definition of a “medically necessary drug”), the ASHP site lists more drug shortages than the FDA site.

American Society of Health-System Pharmacists

As of August 7, 2017, ASHP’s Drug Shortage Resource Center identified 133 drugs in shortage, approximately the same number as at the corresponding time in 2016 (135). In addition, 14 products are not commercially available at all. Seventy-one manufactured drugs have been discontinued since 2010, an increase of two from a year ago. Nearly 85% of drug shortages are generic sterile injectable formulations. The top active shortages by drug class remain antimicrobials, electrolytes and nutritional components, central nervous system agents, chemotherapeutic agents and cardiovascular/autonomic drugs. For a longitudinal view of new drug shortages on an annual basis, and the number of active drug shortages quarterly, see the Appendix. Active shortages include both new and unresolved drug shortages. According to ASHP, the number of new shortages is currently on a par with 2016, and the number of active shortages has stabilized.

US Food and Drug Administration

As of August 7, 2017, the FDA reported that 46 drugs were currently in shortage (compared with 61 one year ago), and 13 other shortages had been resolved. The latter are closely monitored because they may be at risk for falling back into shortage. Based on passage of the Food and Drug Administration Safety and Innovation Act (FDASIA) in 2012, companies are required to notify the FDA of a permanent discontinuance or an interruption in manufacturing of certain drug products six months in advance, or if that is not possible, as soon as practicable. The shortage notification requirement has apparently reduced the number of new shortages by allowing FDA additional time to work with manufacturers to prevent shortages. The FDA’s drug shortages website lists drugs that meet these criteria, reflecting shortage information supplied by manufacturers. A Final Rule published on July 27, 2015, provides further guidance on the notification process and adds biologic products to the requirements for notification about potential supply disruptions.

Drug Shortages Metrics Reported by FDA. The FDA’s fourth annual report on drug shortages (required by FDASIA) noted the following metrics during the first three quarters of calendar year 2016:

- FDA was notified of 186 potential shortage situations by 67 different manufacturers, a 35% increase over the number of potential shortages reported in 2015.
- 64 new drug shortages were prevented in the first three quarters of 2016, a 50% decrease over the comparable time period for 2015.
- The review of 102 generic abbreviated new drug or supplemental applications was expedited, exactly the same as the number reported in 2015.
- 10 inspections were prioritized to address a drug shortage, comparable to the number reported in 2015.
- Three fewer new drug shortages occurred in 2016 (23) compared with 2015 (26); currently, FDA is working to resolve 24 ongoing shortages that began prior to 2016, which is a decrease from the 64 ongoing shortages tracked at the end of 2015 (Personal Communication, Valerie Jensen, RPh, FDA).
FDA exercised regulatory flexibility and discretion in 25 instances affecting 15 medically necessary products. Most of these involved measures to mitigate risks such as the use of filters to remove particulate matter, extra testing for quality, third-party oversight of production, provision of special instructions to prescribers and/or patients, approval of foreign sources, and expanded access to investigational drugs for treatment use. With respect to approval of new foreign sources, the FDA now conducts regular virtual meetings with their international regulatory counterparts to share information on drug shortages and mitigation strategies impacting patients in other countries.

The FDA continues its work to improve its system for data tracking and drug shortage analysis. The FDA released a new technology platform in 2017 for drug manufacturers/applicants to send drug shortage and supply notifications. The “Direct NextGen” platform allows users to login, enter their shortage information, and submit to the FDA. This approach is intended to “streamline day-to-day work to identify and mitigate shortages, including research, data entry, and data management.”

The FDA also has developed apps for both the iPhone and Android operating systems that provide access to drug shortage information as well as notifications about new and resolved drug shortages. Physicians can directly report a drug shortage via the app, the ASHP drug shortage website, or to the Center for Drug Evaluation and Research via email (drugshortages@fda.hhs.gov) or by phone at 240-402-7770.

In late June 2017, the FDA took additional steps to increase competition in the market for prescription drugs and facilitate entry of lower-cost alternatives. The agency published a list of off-patent, off-exclusivity branded drugs without approved generics, and also implemented, for the first time, a new policy to expedite the review of generic drug applications where competition is limited.

STATE OF THE INDUSTRY

Report from Pew Charitable Trusts

Potential economic drivers of drug shortages were previously evaluated by the Council. A new report from Pew Charitable Trusts and the International Society for Pharmaceutical Engineering took a closer look at shortages of sterile injectable pharmaceutical products based on interviews with company executives; the main focus areas were market forces, business continuity planning, and supply chain management.

The report confirmed that quality issues continue to be a driving force behind shortages. Examples included FDA-inspection-related delays, delays in active pharmaceutical ingredient acquisition, failure of final product quality to meet good manufacturing practices, and problems arising from transferring the product from development (or in transferring new technology for a legacy product) to commercial manufacturing site. Factors cited by companies that contributed to drug shortages other than quality included market withdrawals, supply chain design, lack of business continuity elements needed to protect against shortages, limited purchaser-manufacturer incentives, limited insight into future market demands, and regulatory challenges impacting facility expansion or upgrading equipment; the latter is especially pertinent for legacy products.
CURRENT PERSPECTIVE

Based on analysis by the Utah Drug Information Service, during the past 2 years, the number of new drug shortages affecting clinicians and patients has been declining, and the number of active and ongoing drug shortages has remained similar (Appendix, Personal Communication, Erin Fox, PharmD). Shortages have stabilized, but even though the number remains elevated, it is significantly lower than 3 to 4 years ago. The fact that a high number of shortages continues to exist has obscured to a certain degree the progress that has been made, largely attributable to manufacturer notification requirements and proactive steps taken by the FDA. These changes have substantially decreased the actual number of shortages by preventing a large number of new ones. Significant progress has been made overall, but this progress has remained largely unnoticed by hospital pharmacists and practicing physicians who continue to experience the effects of ongoing shortages on a daily basis.

Additionally, it is apparent that some difficult challenges to continued progress exist. As previously noted, most drug shortages involve generic sterile injectable formulations and the cause of these shortages is typically manufacturing and quality problems. The 2016 report from the Government Accountability Office (discussed in the 2016 Council report) identified a decline in the number of suppliers, failure of a supplier to comply with manufacturing standards resulting in a warning letter, and manufacturers operating at low profit margins for generic drugs as primary contributing factors. A major contributing factor to this trend was the failure of Boehringer Ingelheim’s BenVenue manufacturing facility in Bedford, Ohio, in 2013, which at the time was one of the largest suppliers of sterile injectable drugs, including many cancer chemotherapy products. The failure occurred despite the investment of $350 million to upgrade the facility; facing projected deficits of at least $750 million, the facility was not profitable and was closed.

Currently, the majority of sterile injectables for the US market are produced by Pfizer (Hospira), Fresenius Kabi (Akorn), Teva and Baxter; other contributors are American Regent (Luitpold), Sandoz, and Mylan. Pfizer completed its acquisition of Hospira, at the time the largest manufacturer of sterile injectable in the United States, in September 2015. Recent events have created a climate of worsening drug shortages for critical care and emergency medications as well as some of what would be considered “basic products” emanating from the Hospira portfolio. In April 2017, Pfizer notified clinicians about a shortage of pre-packaged emergency drug syringes including atropine, dextrose, epinephrine, and sodium bicarbonate. In June, Pfizer recalled 42 lots of sodium bicarbonate vials (approximately half of supplies) due to concerns that the product may not be sterile; succinylcholine was also impacted by this recall. Most recently, Pfizer had to halt production of 30 different Carpuject™ products (morphine, hydromorphone, etc.) due to problems at a specific manufacturing facility. Vial substitutes exist for most of the Carpuject™ products, but there may be shortages later this year. In response, the FDA extended expiration dating for emergency syringes, approved another supplier of sodium bicarbonate, and also allowed imported sodium bicarbonate.

Although attention remains focused on injectable products, shortages of some solid dosage forms, including atenolol, furosemide, and methylphenidate tablets also have created problems for clinical management this year.

CONCLUSION

The generic sterile injectable drug industry is fragile and some drug supplies for acutely and critically ill patients in the United States remain vulnerable despite industry and federal efforts. Until new and reliable production capacity for sterile injectables is developed, the situation will not
appreciably improve. Some progress is being made, but permanent solutions remain elusive and beyond the control of individual practitioners and the health care system. As long as a free market economy exists and no one entity, including the FDA can mandate that a company produce a specific product, drug shortages will exist into the foreseeable future as the industry continues to merge and contract (except for high cost specialty drugs), the number of drugs emerging off patent increases each year, and the profit margin for legacy products disappears. This dynamic is occurring at the same time that pharmaceutical companies are under increasing pressure to reduce drug costs. The recent acquisition of Hospira by Pfizer and the resulting shortages raises the issue of how such acquisitions or mergers might impact the likelihood of such shortages.

RECOMMENDATION

The Council recommends that Policy H-100.956 be amended by addition 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 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 Health and Human Services 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 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 Centers for Medicare & Medicaid Services 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 partners 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. (Modify Current HOD Policy)

Fiscal Note: Less than $500
REFERENCES

### Table 1. Contrasting the FDA (CDER) and ASHP Drug Shortage Websites

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<thead>
<tr>
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<th>FDA</th>
<th>ASHP</th>
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<tbody>
<tr>
<td><strong>Purpose</strong></td>
<td>Provides information obtained from manufacturers about current shortages, estimated duration, and discontinuations and provides information about FDA’s and other stakeholders’ roles in addressing and preventing shortages</td>
<td>Notification of new shortages and status of ongoing shortages; drug shortage management resources</td>
</tr>
<tr>
<td><strong>Audience</strong></td>
<td>Public</td>
<td>Healthcare practitioners</td>
</tr>
<tr>
<td><strong>Scope of shortage list</strong></td>
<td>All drugs are listed that are confirmed to be a national shortage by FDA. A shortage is considered to be the period of time when the demand for the drug within the United States exceeds the supply of the drug.(^a)</td>
<td>All drug and biologic shortages reported and confirmed with manufacturer that are national in impact.</td>
</tr>
<tr>
<td><strong>Source of shortage report</strong></td>
<td>Manufacturers notify FDA of production disruption and voluntarily provide updates. Reports are also received from ASHP and from public via <a href="mailto:drugshortages@cdr.fda.gov">drugshortages@cdr.fda.gov</a> Note: Manufacturer-provided information represents shortage status at drug firm level.</td>
<td>Voluntary reports from practitioners, patients, pharmaceutical industry representatives and others <strong>Note 1</strong>: Information is updated based on release dates from manufacturers. <strong>Note 2</strong>: Reports reflect status at healthcare provider level.</td>
</tr>
<tr>
<td><strong>Criteria for inclusion on list</strong></td>
<td>Manufacturers cannot meet current market demand for the drug based on information provided by manufacturers and market sales research. Drug listed are defined as “medically necessary.”</td>
<td>(1) Shortage is verified with manufacturers and (2) affects how pharmacy prepares or dispenses a product, or (3) requires use of alternative drugs, which may affect patient care.</td>
</tr>
<tr>
<td><strong>Criteria for resolving shortage</strong></td>
<td>One or more manufacturers are in production and able to meet full market demand.</td>
<td>All manufacturers of the drug restore all formulations and dosage sizes to full availability. Note: Products are listed despite partial or restricted availability as supply chain disruptions can result in intermittent shortages at the provider or patient level.</td>
</tr>
<tr>
<td><strong>Reason for shortage</strong></td>
<td>Provided by manufacturers using reasons required by legislation.(^b) FDA encourages firms to provide additional information about reasons and other information which, if proprietary, is nondisclosable without the firm’s permission.</td>
<td>Provided by manufacturer, if willing to disclose. Note: May differ from FDA’s due to different sources of information and legislation requiring FDA to use specified reasons</td>
</tr>
<tr>
<td><strong>Other information</strong></td>
<td>Estimated duration, links to regulatory information such as recalls and Dear Healthcare Provider Letters</td>
<td>Estimated duration, list of available products, implications for patient care and safety, shortage management strategies, therapeutic alternatives</td>
</tr>
</tbody>
</table>

\(^a\) Note: A separate shortage webpage for vaccines and some biologics is maintained by the Center for Biologics Evaluation and Research.  
\(^b\) Categories include (a) requirement related to complying with good manufacturing practices; (b) regulatory delay; (c) shortage of an active ingredient
APPENDIX

National Drug Shortages
New Shortages by Year
January 2001 to June 30, 2017

Note: Each column represents the number of new shortages identified during that year.
University of Utah Drug Information Service
Erin.Fox@hsc.utah.edu  @foxerlin

National Drug Shortages –
Active Shortages by Quarter

Note: Each column represents the number of active shortages at the end of each quarter.
University of Utah Drug Information Service
Erin.Fox@hsc.utah.edu  @foxerlin
EXECUTIVE SUMMARY

Background. This report responds to Resolution 907-I-16, “Clinical Implications and Policy Considerations of Cannabis Use” introduced by the Resident and Fellow Section and referred by the House of Delegates. Resolution 907 asked that our AMA amend existing policies.

Methods. English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from March 2013 to July 2017 using the search terms as outlined in the body of the report. The 2017 report of the National Academies of Sciences, Engineering, and Medicine (National Academies) on the health effects of cannabis and cannabinoids as well as reports developed by state agencies regarding the impact of legalizing recreational cannabis were also utilized in developing this report.

Results. The National Academies published a comprehensive report on the health effects of cannabis in January 2017. The report found conclusive or substantial evidence that cannabis or cannabinoids have some therapeutic benefits; the report also found substantial or conclusive evidence of a statistical association between cannabis smoking and health harms. The findings of a systematic review on the analgesic effects of cannabis released subsequent to the National Academies report were inconsistent with the National Academies report, which highlights the lack of agreement on this issue, and serves as a source of confusion among physicians, patients, and the public and demonstrates the need for additional research.

Legalizing the recreational use of cannabis may result in increased use over time due to changes in perceptions of safety and health risks. Existing data, although limited, have yet to confirm this pattern of use for children and adolescents. However, cannabis use has increased in adults and pregnant women. Data from jurisdictions that have legalized cannabis demonstrate concerns around unintentional pediatric exposures as well as an increase in traffic deaths due to cannabis-related impaired driving. Limited data also show a decrease in cannabis-related treatment admissions as well as a possible decrease in the use of opioids for chronic pain. Limited data suggest convictions for possession of cannabis may decline in states that legalize cannabis. States have also experienced an increase in governmental revenue through sales and excise taxes on retail cannabis.

Conclusion. The evidence available at this time does not support a substantial change in the AMA’s policy on cannabis. Ongoing surveillance to determine the impact of cannabis legalization and commercialization on public health and safety will be critical. Surveillance should include, but not be limited to the impact on patterns of use, traffic fatalities and injuries, emergency department visits and hospitalizations, unintentional exposures, exposure to second-hand smoke, and cannabis-related treatment admissions. At-risk populations, including pregnant women and children, should be a focus of attention. Continued evaluation of the effectiveness of regulations developed to ensure public health and safety in states that have legalized the medical and/or recreational use of cannabis is necessary. Jurisdictions that have legalized cannabis should allocate a substantial portion of their cannabis tax revenue for public health purposes, including: substance abuse prevention and treatment programs, cannabis-related educational campaigns, scientifically rigorous research on the health effects of cannabis, and public health surveillance efforts.
Subject: Clinical Implications and Policy Considerations of Cannabis Use (Resolution 907-I-16)

Presented by: Robert A. Gilchick, MD, MPH, Chair

Referred to: Reference Committee K (L. Samuel Wann, MD, Chair)

INTRODUCTION

Resolution 907-I-16, “Clinical Implications and Policy Considerations of Cannabis Use,” introduced by the Resident and Fellow Section and referred by the House of Delegates, asked that our AMA amend Policy H-95.998 by addition and deletion to read as follows:

H-95.998 AMA Policy Statement on Cannabis
Our AMA believes that (1) cannabis is a dangerous drug and as such is a public health concern; (2) sale of cannabis should not be legalized; (3) public health based strategies, rather than incarceration, should be utilized in the handling of individuals possessing cannabis for personal use; and (4) additional research should be encouraged (Modify Current HOD Policy),

and amend Policy D-95.976 by deletion to read as follows:

D-95.976 Cannabis - Expanded AMA Advocacy
1. Our AMA will educate the media and legislators as to the health effects of cannabis use as elucidated in CSAPH Report 2, I-13, A Contemporary View of National Drug Control Policy, and CSAPH Report 3, I-09, Use of Cannabis for Medicinal Purposes, and as additional scientific evidence becomes available. 2. Our AMA urges legislatures to delay initiating full legalization of any cannabis product until further research is completed on the public health, medical, economic and social consequences of use of cannabis and, instead, support the expansion of such research. 3. Our AMA will also increase its efforts to educate the press, legislators and the public regarding its policy position that stresses a "public health", as contrasted with a "criminal," approach to cannabis. 4. Our AMA shall encourage model legislation that would require placing the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. It has no scientifically proven, currently accepted medical use for preventing or treating any disease process in the United States." (Modify Current HOD Policy)

The Council on Science and Public Health (Council) has issued four previous reports on cannabis (1997, 2001, 2009, and 2013) establishing a broad policy base. This report focuses on the health effects (both therapeutic and harmful) of cannabis and reviews available data on the impact of legalization. While the AMA prefers to use the scientific term “cannabis,” the colloquial term
“marijuana” is used interchangeably in this report, for example, when quoting a source or identifying the official name of a committee.

METHODS

English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from March 2013 to July 2017 using the search terms “marijuana or cannabis” in combination with “health,” “mental health,” “health effects,” “therapeutic use,” “therapeutic benefits,” “legalization,” “youth or adolescents,” “edibles,” “driving,” “taxes,” and “treatment.” 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 were reviewed for relevant information.

CURRENT AMA AND FEDERATION POLICY

Existing AMA policy on cannabis states that it is a dangerous drug and as such is a public health concern (H-95.998). The AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy (D-95.952). The AMA also urges that marijuana’s status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines (D-95.952). The AMA also believes that public health based strategies, rather than incarceration, should be utilized in the handling of individuals possessing cannabis for personal use (H-95.998).

The AMA believes that the sale of cannabis should not be legalized (H-95.998) and urges legislatures to delay initiating full legalization of any cannabis product until further research is completed on the public health, medical, economic, and social consequences of recreational use (D-95.976). The AMA supports requiring the following warning on all cannabis products not approved by the U.S. Food and Drug Administration, “Marijuana has a high potential for abuse. It has no scientifically proven, currently accepted medical use for preventing or treating any disease process in the United States” (D-95.976). The AMA also advocates for regulations requiring point-of-sale warnings and product labeling for cannabis and cannabis-based products regarding the potential dangers of use during pregnancy and breastfeeding (H-95.936). The AMA supports increased educational programs relating to use and abuse of alcohol, marijuana, and controlled substances (H-170.992). (see Appendix A)

Many medical societies in the Federation have taken positions that are consistent with AMA policy. The California Medical Association (CMA) is one exception. It is on record as urging the legalization and regulation of cannabis to allow for greater clinical research, oversight, accountability, and quality control. CMA believes that the most effective way to protect the public’s health is to tightly control, track, and regulate cannabis and to comprehensively research and educate the public on its health impacts, not through ineffective prohibition.

STATE LAWS ON CANNABIS

At the state level, trends in law have moved from decriminalization, to the legalization of medical use of cannabis, to cannabis regulated for adult recreational use. California was the first jurisdiction in the United States (U.S.) to legalize the medical use of cannabis. Today, 29 states, the District of Columbia (D.C.), Guam, and Puerto Rico have legalized the medical use of cannabis through either the legislative process or ballot measures. These laws vary greatly by jurisdiction from how patients access the product (home cultivated or dispensary), to qualifying conditions,
product safety and testing requirements, packaging and labeling requirements, and consumption method (some states prohibit smoking the product). In jurisdictions that have legalized cannabis for medicinal use, physicians can “certify” or “recommend” a qualifying patient for the medicinal use of cannabis, but physicians cannot prescribe cannabis for medical purposes because it is illegal under federal law. In recent years, an additional 17 states have enacted laws allowing access to low delta-9-tetrahydrocannabinol (THC)/high cannabidiol (CBD) products for children with epilepsy.7

In 2012, Colorado (CO) and Washington (WA) were the first U.S. jurisdictions to legalize the adult use of cannabis for recreational purposes.5,9 Today, a total of 8 states and D.C. have legalized cannabis for recreational purposes, all through the ballot measure process.7 (Figure 1) Most of these jurisdictions have created for-profit, commercial cannabis production and distribution markets where the product is sold and taxed. D.C. is the exception; they have adopted a “grow and give” model whereby residents are permitted to possess, use, grow, and give away cannabis, but they cannot sell it.10 In 2017, legislatures in 20 states introduced legislation to legalize cannabis for recreational use. Vermont’s legislature was the first in the country to vote in favor of legalizing cannabis for recreational use.11 The bill was ultimately vetoed by the governor due to the lack of provisions to protect public health and safety. Specifically, he called on policymakers to hold off on moving forward with commercialization until the state could:

…detect and measure impairment on our roadways, fund and implement additional substance abuse prevention education, keep our children safe and penalize those who do not, [and] measure how legalization impacts mental health and substance abuse issues our communities are already facing.12

RELEVANT FEDERAL LAW AND POLICY

Under the U.S. Controlled Substances Act (CSA) of 1970, cannabis is classified as a Schedule I controlled substance, meaning it has no currently accepted medical use in treatment in the United States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.13 In 2011, the governors of Washington and Rhode Island petitioned the Drug Enforcement Administration (DEA) asking it to change cannabis from a Schedule I to a Schedule II drug under the CSA. In August of 2016, the DEA announced that cannabis would remain a Schedule I controlled substance.14 The notice stated that:

The DEA and FDA continue to believe that scientifically valid and well-controlled clinical trials conducted under investigational new drug applications are the proper way to research all potential new medicines, including marijuana. Furthermore, we believe that the drug approval process is the proper way to assess whether a product derived from marijuana or its constituent parts is safe and effective for medical use.14

Cannabis is not FDA-approved as a safe and effective drug for any indication. However, the agency has approved three drug products containing synthetic versions of the main psychoactive ingredient of cannabis, THC. Marinol® and Syndros™, which include the active ingredient dronabinol, are indicated for nausea and vomiting associated with cancer chemotherapy and anorexia associated with weight loss in patients with AIDS.15 Cesamet®, which contains the active ingredient nabilone, also is indicated for the treatment of the nausea and vomiting associated with cancer chemotherapy.15 Clinical investigations are underway for one CBD-based product, Epidiolex® for Lennox-Gastaut syndrome and Dravet syndrome and the THC/CBD combination product Sativex® for cancer pain.15,16
In 2016, the DEA announced a change in policy designed to increase the number of DEA-registered cannabis manufacturers. Currently the University of Mississippi is the only entity authorized to produce cannabis for research purposes in the United States. The new policy will allow additional entities to submit applications and become registered with the DEA to grow and distribute cannabis for FDA-authorized research purposes.17

Under the Obama Administration, a memorandum to all U.S. Attorneys outlined cannabis enforcement priorities for the federal government. The memo explained that jurisdictions enacting laws legalizing cannabis that also have strong regulatory enforcement systems would be less likely to be threatened with federal enforcement.18 Federal priorities include preventing: (1) the distribution of cannabis to minors; (2) revenue from the sale of cannabis from going to criminal enterprises, gangs, and cartels; (3) the diversion of cannabis from states where it is legal under state law in some form to other states; (4) state-authorized cannabis activity from being used as a cover or pretext for the trafficking of other illegal drugs or other illegal activity; (5) violence and the use of firearms in the cultivation and distribution of cannabis; (6) drugged driving and the exacerbation of other adverse public health consequences associated with cannabis use; (7) the growing of cannabis on public lands and the attendant public safety and environmental dangers posed by cannabis production on public lands; and, (8) cannabis possession or use on federal property.18 Accordingly, if particular conduct threatens federal priorities, that person or entity would be subject to federal enforcement actions.

While the Obama Administration tolerated state laws legalizing cannabis, it is still unclear how the Trump Administration will handle the issue.19 In July of 2017, the Attorney General sent letters to four governors warning them that he had “serious concerns” about the effects of cannabis legalization, raising questions as to whether the current compromise on enforcement with the Justice Department may be under reconsideration.20

THE HEALTH EFFECTS OF CANNABIS

The National Academies of Sciences, Engineering, and Medicine (National Academies) published a comprehensive report in January 2017 commissioned by federal, state, philanthropic, and nongovernmental organizations, entitled “The Health Effects of Cannabis and Cannabinoids: The Current State of Evidence and the Recommendations for Research.” The report’s recommendations outline priorities for a research agenda and highlight the potential for improvements in data collection efforts and enhanced surveillance capacity. The report also contained 98 conclusions based on the accumulated evidence related to cannabis or cannabinoid use and health.6 (see Appendix B)

The report examined a broad range of possible health effects of cannabis and cannabinoids. Health effects examined included those related to cancer; cardiometabolic risk; respiratory disease; immunity; injury and death; prenatal, perinatal, and neonatal exposure; psychosocial and mental health; problem cannabis use; and cannabis use and the misuse of other substances. The findings are organized into 5 evidence categories: conclusive, substantial, moderate, limited, and no/insufficient evidence. The report found conclusive or substantial evidence that cannabis or cannabinoids are effective: (1) for the treatment of chronic pain in adults (cannabis); (2) as antiemetics in the treatment of chemotherapy-induced nausea and vomiting (oral cannabinoids); and (3) for improving patient-reported multiple sclerosis spasticity symptoms (oral cannabinoids).6 The report also found substantial evidence of a statistical association between cannabis smoking and: (1) more frequent chronic bronchitis episodes (long-term cannabis smoking); (2) increased risk of motor vehicle crashes; (3) lower birth weight of offspring (maternal cannabis smoking); and
(4) the development of schizophrenia or other psychoses, with the highest risk among the most frequent users. A systematic review published subsequent to the National Academies report examined 27 clinical trials involving patients with chronic pain and found limited evidence that cannabis may alleviate neuropathic pain in some patients, but that insufficient evidence exists to demonstrate analgesic effects in patients with other types of chronic pain. This conclusion contradicts the finding of the National Academies report and is an example of how research findings on the therapeutic effects of cannabis remain inconsistent, leading to confusion among physicians, patients, the media, policy makers, and others.

IMPACT OF STATE LEGALIZATION OF CANNABIS

In 2012, CO and WA were the first states to legalize cannabis for recreational use. As jurisdictions continue to follow in their footsteps, many are looking at data from these states to determine the impact of legalization on public health and safety. Issues being examined include the impact of legalization on patterns of use by adults, children and adolescents, and pregnant women; cannabis-related exposures; cannabis-related hospital or emergency department visits; cannabis-related treatment admissions; impaired driving; crime; opioid use; and governmental costs and revenue. Since regulatory structures governing cannabis vary by jurisdiction and continue to evolve, the impact on health and safety is difficult to discern. It is also worth noting that although recreational use of cannabis was first legalized in 2012, cannabis products for recreational use were not commercially available for sale in CO or WA until 2014. Alaska (AK), D.C., and Oregon (OR) voted to legalize recreational use in 2014. While OR allowed limited sales of cannabis through medical dispensaries in 2015, cannabis dispensaries for recreational users did not open in AK or OR until 2016 (Figure 2). As a result, limited data are currently available to determine the overall impact of legalizing recreational cannabis use on specific outcome measures.

The Colorado Department of Public Health and Environment (CDPHE) appointed a Retail Marijuana Public Health Advisory Committee (RMPHAC), to review scientific literature on the health effects of cannabis and state-specific health outcomes and patterns of use. The RMPHAC report was informed by state-based data and national surveys such as the Substance Abuse and Mental Health Services Administration’s (SAMHSA) National Survey on Drug Use and Health (NSDUH) and the Center for Disease Control and Prevention’s (CDC) Behavioral Risk Factor Surveillance System (BRFSS) and Pregnancy Risk Assessment Monitoring System (PRAMS). The Washington State Institute for Public Policy (WSIPP) has conducted a benefit-cost analysis of the implementation of WA Initiative 502 as required by law. The Northwest High Intensity Drug Trafficking Area (NWHIDTA) and the Rocky Mountain High Intensity Drug Trafficking Area (RMHIDTA) have also issued reports on the impacts of the legalization of cannabis in WA and CO, respectively. The results from these reports were utilized in examining the impact of cannabis legalization on public health and safety.

Use among Adults

In the United States, cannabis is the most commonly used illicit drug. Overall, from 2002-2014, the prevalence of cannabis use during the past month, past year, and daily or almost daily increased among persons aged 18 years and older. In 2016, the percentage of young adults (18-25 years) who were current marijuana users (past month) was similar to the percentages in 2014 and 2015, while the percentage of older adults (≥ 26 years) who were current users continued to increase.
The percentage of young Coloradan adults aged 18 to 25 years reporting cannabis use within the past year increased significantly after “medical” cannabis legalization (35 percent in 2007 to 2008 to 43 percent in 2010 to 2011). The latest data available suggest cannabis use has remained fairly constant in CO (45 percent in 2013-2014). In 2015, based on the BRFSS data, 13 percent of CO adults ages 18 and up had used cannabis in the past-month. The NSDUH estimate for past-month use is higher, at 17 percent. However, neither survey showed a statistical change from 2014 to 2015. According to NSDUH data, adult use of cannabis in CO has continued to be higher than the national average, which was 8 percent. In WA, young adults’ (18-25 years) past-year cannabis use was 6 percent higher than the nation’s in 2012-2013, and adults’ use (≥ 26 years) was 5 percent higher. Past month use of cannabis was 5 percent higher than the nation’s average for young adults and adults in 2012-2013. Statewide BRFSS data indicate that since the legalization of recreational cannabis in WA, use has increased among adults.

Use among Pregnant Women

Cannabis is the most commonly used illicit drug during pregnancy. The movement toward the legalization of cannabis may result in more women using cannabis during pregnancy. Cannabis crosses the placenta and is found in breast milk. It may have adverse effects on both perinatal outcomes and fetal neurodevelopment, though evidence is limited. In 2015, the American College of Obstetricians and Gynecologists issued a committee opinion discouraging physicians from suggesting the use of marijuana during preconception, pregnancy, and lactation.

Overall, cannabis use during pregnancy is increasing with 3.85 percent of pregnant women between the ages of 18 and 44 years reporting past-month cannabis use in 2014, compared with 2.37 percent in 2002. PRAMS data for CO showed that among new mothers, 11.2 percent used cannabis prior to pregnancy, 5.7 percent used cannabis during pregnancy, and 4.5 percent of breastfeeding mothers used cannabis after delivery. Cannabis use during pregnancy was statistically higher among women with an unintended pregnancy (9.1 percent) than among women who intended to become pregnant (4.0 percent). When cannabis use during pregnancy was compared among different demographics, both education and age showed statistical differences, whereas race and ethnicity did not.

Use among Adolescents

Adolescents are of particular interest in cannabis-policy discussions because the negative health effects of the drug are heightened when use begins in adolescence. In addition to the health effects, including the increased risk of addiction, evidence also suggests that cannabis use in adolescence and early adulthood is associated with poor social outcomes, including unemployment, lower income, and lower levels of life and relationship satisfaction. Changes in the legal status of cannabis may affect use among adolescents by decreasing the perceived risk of harm or through the marketing of legal cannabis. Studies examining the impact of “medical” cannabis laws found no measurable effect on the patterns of adolescent cannabis use. States with recreational or adult use cannabis laws also have not experienced an increase in adolescent use in the short term. However, further surveillance is necessary to determine long-term results.

NSDUH data for 2016 suggest that 6.5 percent or 1.6 million adolescents (12-17 years) were current (past month) users of cannabis. The percentage of adolescents who were current cannabis users in 2016 was lower than the percentages in most years from 2009 to 2014, but was similar to the percentage in 2015. In CO, estimates of current cannabis use (2002-2015) among high school students have fluctuated between approximately 20 percent and 25 percent. Survey results from 2015 indicate that approximately 38 percent of CO high school students reported having ever used
cannabis and 21 percent reported use in the past 30 days. These estimates are similar to national estimates of ever and current cannabis use among high school students. Among CO middle school students in 2015, an estimated 7.6 percent had ever used cannabis and an estimated 4.4 percent reported currently using cannabis. In WA, the Healthy Youth Survey, found that cannabis use indicators across grades 6, 8, 10, and 12, have been stable or fallen slightly since the legalization of recreational cannabis.

Cannabis-Related Exposures

Cannabis-related exposures generally refer to the number of human exposures related to accidental or excessive consumption or inhalation of cannabis and cannabis edibles. Early data from states that have legalized cannabis have shown an increase in calls to poison control centers related to cannabis exposures. According to the WA State Poison Control Center (WAPC), calls related to cannabis exposure nearly doubled from 2011 (n=146) to 2016 (n=286). In 2016, over 42 percent (n=120) of the total cannabis-related calls involved individuals 13-29 years of age who had been exposed to some form of cannabis. Over 70 percent (n=226) of patients were exposed to cannabis through ingestion.

In CO, 7.9 percent of adults with children 1-14 years old in the home reported having cannabis or cannabis products in or around the home (2015). It was estimated that approximately 14,000 homes in CO with children 1-14 years old had cannabis in the home with potentially unsafe storage. Cannabis-related exposures in CO increased 100 percent in the three-year average (2013-2015) since CO legalized recreational use of cannabis compared to the three-year average (2010-2012) prior to legalization. In children (≤ 5 years old), cannabis-related exposures increased 169 percent after legalization of recreational cannabis in CO. However, overall human exposures reported to Rocky Mountain Poison Center involving cannabis were marginally lower in 2016 (n=224) compared with 2015 (n=231).

A retrospective cohort study of CO children’s hospital admissions and regional poison control (RPC) cases for cannabis exposures between January 1, 2009, and December 31, 2015, found that hospital visits and RPC case rates for cannabis exposures in patients under 10 years of age increased between the 2 years prior to and the 2 years after legalization. During this time period, RPC calls increased at a significantly higher rate in CO than in the rest of the U.S. (34 percent vs. 19 percent per year). In CO, edible products were responsible for more than half of the exposures.

Cannabis Secondhand Smoke Exposure

For 2014 and 2015 together, 3.2 percent of adults with children 1-14 years old reported cannabis being used inside the home in CO. Of these, 83.2 percent reported the cannabis was smoked, vaporized, or dabbed (dabs are a highly concentrated extract of THC). It is estimated that approximately 16,000 homes in CO had children 1-14 years old with possible exposure to secondhand cannabis smoke or vapor in the home.

Cannabis-Related Emergency Department Visits and Hospital Admissions

In addition to hospitalizations for unexpected pediatric exposure to cannabis, increased cannabis use after legalization has resulted in an increase in the number of ED visits and hospitalizations related to acute marijuana intoxication. Retrospective data from the CO Hospital Association has shown that the prevalence of hospitalizations for cannabis exposure in patients aged 9 years and older essentially doubled after the legalization of medical cannabis (15 per 100,000 hospitalizations...
in 2001 to 2009 versus 28 per 100,000 hospitalizations from 2010 to 2013) and that cannabis-related ED visits nearly doubled after the legalization of recreational cannabis (22 per 100,000 ED visits in 2010 to 2013 versus 38 per 100,000 ED visits from January to June of 2014).

Cannabis legalization may also eventually contribute to increased ED visits for the sequelae of chronic cannabis use, including cannabinoid hyperemesis syndrome. Patients with cannabinoid hyperemesis present to the ED with periodic bouts of intractable vomiting that are unresponsive to traditional antiemetics. CO saw a doubling of ED visits for cyclic vomiting after the legalization of medical cannabis in CO in 2009, although the total number of visits remained small.

**Cannabis-Related Treatment Admissions**

Limited data is available regarding the impact of laws legalizing the recreational use of cannabis on cannabis-related treatment admissions,* though the early data suggests a decline in treatment admissions. A study of cannabis-related treatment admissions in Denver from 2001-2013 found that such admissions increased from 2005 (2,694) to 2008 (3,295) and then declined by 10.6 percent to 2,887 in 2011. Significant decreases in treatment entries after 2009, a time when access to cannabis through CO’s medical cannabis program was increasing, have been hypothesized to be a reflection of an accepting public opinion of cannabis use resulting in fewer individuals seeking treatment. In WA, cannabis-related treatment admissions fell in the three years following legalization of recreational use dropping from 7,843 in 2012, to 7,374 in 2013, 6,885 in 2014, and 6,142 in 2015. Youth treatment admissions for cannabis have remained between 66 percent and 70 percent of overall admissions in WA state since 2010.

**Impaired Driving**

A potential unintended consequence of legalizing cannabis use for medical or recreational purposes is increased cannabis-related driving impairment. While the effects of alcohol on driving performance and crash risk are well understood, less is known regarding the effects of cannabis on driving. Research, including direct observations made in a driving simulator, has demonstrated the potential of cannabis to impair driving related skills. Individuals driving under the influence of cannabis seem to exhibit a general reckless driving style and cannabis smoking increases the risk of involvement in a motor vehicle accident approximately 2-fold. Cannabis use is associated with slower driving, an increased tendency to drive below the speed limit, increased following distance, increased lane weaving, and increased mean distance headway to the preceding vehicle. These behaviors suggest that those driving under the influence of cannabis are aware of their impairment and decrease their speed to compensate.

Unlike alcohol, THC is not water soluble, but is stored in fatty tissues and released over time. A clear relationship between THC levels and impairment has been difficult to establish, in part, because a urine or even serum level of THC could reflect cannabis used quite remotely from the date of the specimen collection. Peak THC level can occur when low impairment is measured, and high impairment can be measured when THC level is low. Additionally, some individuals may demonstrate little or no impairment at a THC level that impairs someone else.

The most recent data from CO show that cannabis-related traffic deaths increased 48 percent in the three-year average (2013-2015) after recreational use of cannabis was legalized compared with the three-year average (2010-2012) prior to legalization.
Commission found that the number of drivers with THC in their blood involved in fatal driving accidents increased more than 120 percent from 2010 to 2014.\textsuperscript{24} Despite data from these individual states, another study found that three years after recreational cannabis legalization, motor vehicle crash fatality rates overall for WA and CO were not statistically different from those in similar states without recreational cannabis legalization.\textsuperscript{46}

\textit{Criminal Justice}

Legalizing cannabis for recreational use could have variable impacts on crime. Some have argued that legalization could result in a decrease in drug-trafficking and possession charges; others contend that the increased use of cannabis could result in increases in violent crime.

Data from WA’s Administrative Office of the Courts demonstrated that among adult offenders, misdemeanor cannabis possession convictions declined from 297 convictions in January 2012 to 0 by January 2013.\textsuperscript{23} Among youth offenders, misdemeanor cannabis convictions dropped from 1,015 in the first three months of 2012 to 722 in the first quarter of 2013.\textsuperscript{23} WA reports that from 2012 through 2014, cannabis seizure offenses reported to the National Incident-Based Reporting System decreased by nearly 62 percent.\textsuperscript{24} Despite the overall decline in seizures in the state, youth cannabis seizure offenses have not followed this trend. In 2010, youth twelve to seventeen years old represented 28.9 percent (n=855) of all seizures.\textsuperscript{24} In 2012 (legalization), they represented 37.5 percent (n=2,378) of seizures, and in 2013 they represented 68.6 percent (n=1,840) of total seizures.\textsuperscript{24} By the end of 2014 (commercialization), 74 percent (n=1,791) of seizures involved youth aged twelve to seventeen years.\textsuperscript{24}

Crime in Denver and Colorado has increased from 2013 to 2015.\textsuperscript{25} Since 2014, there has been an increase in organized, large-scale home grows for trafficking to states where cannabis is not legalized.\textsuperscript{25} Seizures of Colorado marijuana in the U.S. mail increased 471 percent from an average of 129 pounds (2010-2012) to 736 pounds (2013-2015) over the three-year period after recreational use was legalized.\textsuperscript{25} In addition, in Colorado, property crime increased 6.2 percent, violent crime increased 6.7 percent, and all crime increased 6.2 percent from 2014 to 2015.\textsuperscript{25}

\textit{Opioid Use}

According to the Centers for Disease Control and Prevention, increases in unintentional overdoses and deaths due to prescription opioids and heroin are the biggest driver of the drug overdose epidemic. Studies have found a decrease in the use of opioids among pain patients provided with medical cannabis.\textsuperscript{47} Furthermore, medical cannabis laws are associated with significantly lower state-level opioid overdose mortality rates.\textsuperscript{47} Additional research is necessary to determine how cannabis laws may impact opioid use, morbidity, and mortality.

\textit{Governmental Costs and Revenue}

Cannabis tax collections in CO and WA have continued to increase, and, on a national basis, legalization and associated taxation of cannabis could result in billions of dollars per year of tax revenue for states.\textsuperscript{48} In WA, I-502 required the WA State Liquor and Cannabis Board to oversee the recreational cannabis market and imposed a 25\% excise tax on producers, processors, and retailers, which was later replaced with a 37\% excise tax on retail sales.\textsuperscript{23} The Dedicated Marijuana Account was created for cannabis revenues and expenditures.\textsuperscript{23} Voters were told legalization could bring in as much as $1.9 billion over five years, with 40 percent going to the state general fund and local budgets and the remaining 60 percent intended for substance abuse prevention, research,
education, and health care. As of April 2016, state sales average over $2 million a day, which translates into mean excise tax revenue approaching $270 million per year.48

In CO, voters were initially told cannabis excise taxes would boost state revenues by $70 million per year, with the first $40 million each year to be allocated to school construction, leaving $30 million for enforcement and general state funds.48 Revenues in calendar year 2016 reached nearly $200 million. The CO legislature established a Marijuana Tax Cash Fund (MTCF) in 2014, which collects tax revenue from both medical and recreational cannabis sales. Funds in the MTCF have been appropriated to government agencies to address the possible health and safety consequences of legalization such as monitoring the health effects of cannabis, conducting health education campaigns, and providing substance abuse prevention and treatment programs.

The legalization and commercialization of cannabis results in revenue for states through taxes and fees, but it also comes with costs, both in regulating and enforcement actions and in protecting public health and safety. For example, in Colorado, the Marijuana Enforcement Division (MED) is responsible for regulating both medical and recreational cannabis businesses in the state. The MED’s four offices and 55 employees are responsible for rulemaking, licensing and inspecting cannabis-related businesses, and taking enforcement actions. The annual budget for the MED is approximately $10.5 million.

MINIMIZING HEALTH RISKS OF LEGALIZATION

As jurisdictions continue to understand the impact of legalization on health and other outcomes, the regulatory structure governing cannabis will continue to evolve. In CO, CDPHE continues to assess the knowledge gaps related to cannabis and develop policies to protect vulnerable populations.49 For example, the issue of child cannabis exposure from edibles has been concerning. In CO, confusion surrounding the serving size for edible products and the delayed onset of the effects of THC are thought to have contributed to overconsumption.49 Regulations were changed to ensure easier identification of average serving size in a single edible product.49 CO, OR and WA now require a universal symbol to be affixed to edibles. Four states (Alaska, CO, OR, and WA) prohibit the manufacture or packaging of edibles that appeal to youth.50 Concerns remain regarding the regulatory gaps that exist in each of these states and whether these regulations are actually informing consumers and keeping the public safe.50

To address motor vehicle crashes due to driving under the influence of cannabis, some states have established per se limits for driving under the influence of cannabis. For example, CO and WA have established 5 ng/ml of THC as the legal limit for cannabis-impaired driving.49 However, little evidence exists to support the enactment of specific per se limits for cannabis.24 As a first step, states are being encouraged to conduct prevalence studies on the number and proportion of drivers testing positive for THC.24

The Vermont Department of Health has conducted a health impact assessment to determine the potential impact of legislation to regulate and tax cannabis for recreational use on the health of Vermonters and to recommend ways to mitigate the adverse health impacts of such legislation. The recommendations include expanding all current tobacco laws to include cannabis, prohibiting the use of cannabis in public places, standardizing and testing packaging and potency, funding prevention and education, restricting advertising, prohibiting infused products on the regulated market, setting a blood level operating limit for THC, expanding screening for substance use disorders in primary care, training health care providers on the health impacts of cannabis, and funding surveillance and research.51
CONCLUSION

Although the National Academies found conclusive or substantial evidence that cannabis or cannabinoids have some therapeutic benefits, they also found substantial or conclusive evidence of a statistical association between cannabis smoking and health harms. Furthermore, the findings of a systematic review on the analgesic effects of cannabis released subsequent to the National Academies report were inconsistent with the National Academies report, which highlights the lack of agreement on this issue, and serves as a source of confusion among physicians, patients, and the public and demonstrates the need for additional research.

Legalizing the recreational use of cannabis may result in its increased use over time due to changes in perceptions of safety and health risks. Existing data, although limited, have yet to confirm this expectation for children and adolescents. However, cannabis use has increased in adults and pregnant women. Data from jurisdictions that have legalized cannabis demonstrate concerns particularly around unintentional pediatric exposures resulting in increased calls to poison control centers and ED visits as well as an increase in traffic deaths due to cannabis-related impaired driving. Limited data also show a decrease in cannabis-related treatment admissions as well as a possible decrease in the use of opioids for chronic pain. In terms of crime, convictions for the possession of cannabis may decline in states that legalize cannabis. While states have seen an increase in revenue through sales and excise taxes on retail cannabis, the administrative and enforcement costs as well as the costs to society in terms of public health and safety should not be minimized.

Ongoing surveillance to determine the impact of cannabis legalization and commercialization on public health and safety will be critical. Surveillance should include, but not be limited to, the issues covered in this report – impact on patterns of use, traffic fatalities and injuries, emergency department visits and hospitalizations, unintentional exposures, exposure to second-hand smoke, and cannabis-related treatment admissions. There should also be a focus on at-risk populations including pregnant women and children. Continued evaluation of the effectiveness of regulations developed to ensure public health and safety in states that have legalized the medical and/or recreational use of cannabis is necessary. Jurisdictions that have legalized cannabis should allocate a substantial portion of their cannabis tax revenue for public health purposes, including substance abuse prevention and treatment programs, cannabis-related educational campaigns, scientifically rigorous research on the health effects of cannabis, and public health surveillance efforts.

For physicians, legalization may require practice modifications, particularly regarding patient-provider conversations about use and risk. Additional education on counseling patients about the danger of second hand smoke exposure, underage use, safe storage, impaired driving, and the overconsumption of edibles may be warranted.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted in lieu of Resolution 907-I-16 and the remainder of this report be filed:

Cannabis Legalization for Recreational Use
Our AMA: (1) believes that cannabis is a dangerous drug and as such is a serious public health concern; (2) believes that the sale of cannabis for recreational use should not be legalized; (3) discourages cannabis use, especially by persons vulnerable to the drug's effects and in high-risk populations such as youth, pregnant women, and women who are breastfeeding; (3) believes states that have already legalized cannabis (for medical or recreational use or both) should be required take steps to regulate the product effectively in order to protect public health and safety and that laws and regulations related to legalized cannabis use should consistently be evaluated to determine their effectiveness; (5) encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of cannabis use; (6) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use. (New HOD Policy)

Cannabis Legalization for Medicinal Use
Our AMA: (1) believes that scientifically valid and well-controlled clinical trials conducted under federal investigational new drug applications are necessary to assess the safety and effectiveness of all new drugs, including potential cannabis products for medical use; (2) opposes the legalization of cannabis for medicinal use through the state legislative, ballot initiative, or referendum process; (3) will develop model legislation requiring the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. This product has not been approved by the Food and Drug Administration for preventing or treating any disease process."; (4) supports legislation ensuring or providing immunity against federal prosecution for physicians who certify that a patient has an approved medical condition or recommend cannabis in accordance with their state's laws; and (5) believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions. (New HOD Policy)

2. That the following new policy be adopted:

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

3. That Policy H-95.952, “Cannabis for Medicinal Use,” be amended by addition and deletion to read as follows:

H-95.952, “Cannabis Research for Medicinal Use”
(1) Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease. (2) Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product. (3) Our AMA urges the National
Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; c) confirming that cannabis of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support. (4) Our AMA believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions. Our AMA supports research to determine the consequences of long-term cannabis use, especially among youth, adolescents, pregnant women, and women who are breastfeeding. (5) Our AMA urges legislatures to delay initiating the legalization of cannabis for recreational use until further research is completed on the public health, medical, economic, and social consequences of its use. (Modify Current HOD Policy)

4. That Policy H-95.936, “Cannabis Warnings for Pregnant and Breastfeeding Women,” be reaffirmed. (Reaffirm HOD Policy)

5. That Policies H-95.998, “AMA Policy Statement on Cannabis,” H-95.995, “Cannabis Use,” H-95.938, “Immunity from Federal Prosecution for Physicians Recommending Cannabis,” and D-95.976, “Cannabis – Expanded AMA Advocacy,” be rescinded since they have been implemented, were duplicative of another policy, or portions were incorporated into new policies proposed in this report. (Rescind HOD Policy)

Fiscal Note: Less than $1,000
FIGURE 1
Status of State Laws on Cannabis Legalization (Source: ASTHO)

FIGURE 2
Timeline of State Recreational Cannabis Laws

- 2012 • CO, WA legalize recreational cannabis
- 2013
- 2014 • CO, WA recreational cannabis sales begin
  • AK, DC, OR legalize recreational cannabis
- 2015 • OR recreational cannabis sales begin
- 2016 • AK recreational sales begin
  • CA, MA, ME, NV vote to legalize recreational cannabis
- 2017 • NV recreational sales begin
- 2018 • CA, MA, ME recreational sales expected to begin
REFERENCES

   American Medical Association, Interim Meeting, Houston, TX, November 2009.

   Policy. American Medical Association, Interim Meeting, National Harbor, MD, November
   2013.

3 Council on Scientific Affairs Report 6. Medical marijuana. American Medical Association,

4 Council on Scientific Affairs Report 10. Medical marijuana. American Medical Association,
   Interim Meeting, Dallas, TX, December 1997.

5 California Medical Association. CA Medical Association announces support for responsible

6 The National Academies of Sciences Engineering and Medicine. The health effects of cannabis
   and cannabinoids: Current state of evidence and recommendations for research.

   22, 2017.

8 CO Amendment 64. (2012).


12 Phillip B.Scott. VT S. 22 Veto Message. 2017. http://legislature.vermont.gov/assets/All-Senate-

13 21 USC 812.

14 81 FR 53687.

   18, 2017.


17 81 FR 53846.


APPENDIX A
Existing AMA Policies Related to Cannabis

D-95.976, “Cannabis - Expanded AMA Advocacy”
1. Our AMA will educate the media and legislators as to the health effects of cannabis use as elucidated in CSAPH Report 2, I-13, A Contemporary View of National Drug Control Policy, and CSAPH Report 3, I-09, Use of Cannabis for Medicinal Purposes, and as additional scientific evidence becomes available. 2. Our AMA urges legislatures to delay initiating full legalization of any cannabis product until further research is completed on the public health, medical, economic and social consequences of use of cannabis and, instead, support the expansion of such research. 3. Our AMA will also increase its efforts to educate the press, legislators and the public regarding its policy position that stresses a "public health", as contrasted with a "criminal," approach to cannabis. 4. Our AMA shall encourage model legislation that would require placing the following warning on all cannabis products not approved by the U.S. Food and Drug Administration: "Marijuana has a high potential for abuse. It has no scientifically proven, currently accepted medical use for preventing or treating any disease process in the United States.” Res 213, I-14.

H-95.952, “Cannabis for Medicinal Use”
(1) Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease. (2) Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product. (3) Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; c) confirming that cannabis of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support. (4) Our AMA believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions. CSA Rep. 10, I-97, Modified: CSA Rep. 6, A-01, Modified: CSAPH Rep. 3, I-09, Modified in lieu of Res. 902, I-10, Reaffirmed in lieu of Res. 523, A-11, Reaffirmed in lieu of Res. 202, I-12, Reaffirmed: CSAPH Rep. 2, I-13.

H-95.998, “AMA Policy Statement on Cannabis”
Our AMA believes that (1) cannabis is a dangerous drug and as such is a public health concern; (2) sale of cannabis should not be legalized; (3) public health based strategies, rather than incarceration, should be utilized in the handling of individuals possessing cannabis for personal use; and (4) additional research should be encouraged. BOT Rep. K, I-69, Reaffirmed: CLRPD
H-95.995, “Cannabis Use”

H-95.936, “Cannabis Warnings for Pregnant and Breastfeeding Women”
Our AMA advocates for regulations requiring point-of-sale warnings and product labeling for cannabis and cannabis-based products regarding the potential dangers of use during pregnancy and breastfeeding wherever these products are sold or distributed. Res. 922, I-15.

H-95.938, “Immunity from Federal Prosecution for Physicians Recommending Cannabis”
Our American Medical Association supports legislation ensuring or providing immunity against federal prosecution for physicians who certify that a patient has an approved medical condition or recommend cannabis in accordance with their state's laws. Res. 233, A-15.

H-95.997, “Cannabis Intoxication as a Criminal Defense”

H-170.992, “Alcohol and Drug Abuse Education”
Our AMA: (1) supports continued encouragement for increased educational programs relating to use and abuse of alcohol, marijuana and controlled substances; (2) supports the implementation of alcohol and marijuana education in comprehensive health education curricula, kindergarten through grade twelve; and (3) encourages state medical societies to work with the appropriate agencies to develop a state-funded educational campaign to counteract pressures on young people to use alcohol. Sub. Res. 63, I-80 Reaffirmed: CLRPD Rep. B, I-90 Reaffirmation and Reaffirmed: Sunset Report, I-00 Appended: Res. 415, I-01 Reaffirmed: CSAPH Rep. 1, A-11.
## APPENDIX B

The National Academies of Sciences, Engineering, and Medicine


### EVIDENCE

<table>
<thead>
<tr>
<th>CONCLUSIONS FOR THERAPEUTIC EFFECTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>• For the treatment for chronic pain in adults (cannabis)</td>
</tr>
<tr>
<td>• Antiemetics in the treatment of chemotherapy-induced nausea and vomiting (oral cannabinoids)</td>
</tr>
<tr>
<td>• For improving patient-reported multiple sclerosis spasticity symptoms (oral cannabinoids)</td>
</tr>
<tr>
<td>• Improving short-term sleep outcomes in individuals with sleep disturbance associated with obstructive sleep apnea syndrome, fibromyalgia, chronic pain, and multiple sclerosis (cannabinoids, primarily nabiximols)</td>
</tr>
<tr>
<td>• Increasing appetite and decreasing weight loss associated with HIV/AIDS (cannabinoids and oral cannabinoids)</td>
</tr>
<tr>
<td>• Improving clinician-measured multiple sclerosis spasticity symptoms (oral cannabinoids)</td>
</tr>
<tr>
<td>• Improving symptoms of Tourette syndrome (THC capsules)</td>
</tr>
<tr>
<td>• Improving anxiety symptoms, as assessed by a public speaking test, in individuals with social anxiety disorders (cannabidiol)</td>
</tr>
<tr>
<td>• Improving symptoms of posttraumatic stress disorder (nabiximols)</td>
</tr>
<tr>
<td>• Better outcomes (i.e., mortality, disability) after a traumatic brain injury or intracranial hemorrhage.</td>
</tr>
<tr>
<td>• Improving symptoms associated with dementia (cannabinoids)</td>
</tr>
<tr>
<td>• Improving intraocular pressure associated with glaucoma (cannabinoids)</td>
</tr>
<tr>
<td>• Reducing depressive symptoms in individuals with chronic pain or multiple sclerosis (nabiximols, dronabinol, and nabilone)</td>
</tr>
<tr>
<td>• Cancers, including glioma (cannabinoids)</td>
</tr>
<tr>
<td>• Cancer-associated anorexia cachexia syndrome and anorexia nervosa (cannabinoids)</td>
</tr>
<tr>
<td>• Symptoms of irritable bowel syndrome (dronabinol)</td>
</tr>
<tr>
<td>• Epilepsy (cannabinoids)</td>
</tr>
<tr>
<td>• Spasticity in patients with paralysis due to spinal cord injury (cannabinoids)</td>
</tr>
<tr>
<td>• Symptoms associated with amyotrophic lateral sclerosis (cannabinoids)</td>
</tr>
<tr>
<td>• Chorea and certain neuropsychiatric symptoms associated with Huntington’s disease (oral cannabinoids)</td>
</tr>
<tr>
<td>• Motor system symptoms associated with Parkinson’s disease or the levodopa-induced dyskinesia (cannabinoids)</td>
</tr>
<tr>
<td>• Dystonia (nabilone and dronabinol)</td>
</tr>
<tr>
<td>• Achieving abstinence in the use of addictive substances (cannabinoids)</td>
</tr>
<tr>
<td>• Mental health outcomes in individuals with schizophrenia or schizophreniform psychosis (cannabidiol)</td>
</tr>
</tbody>
</table>

### EVIDENCE FOR CANCER

<table>
<thead>
<tr>
<th>CONCLUSIONS FOR CANCER</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Incidence of lung cancer (cannabis smoking)</td>
</tr>
<tr>
<td>• Incidence of head and neck cancers</td>
</tr>
<tr>
<td>• Non-seminoma-type testicular germ cell tumors (current, frequent, or chronic cannabis smoking)</td>
</tr>
<tr>
<td>• Incidence of esophageal cancer (cannabis smoking)</td>
</tr>
</tbody>
</table>
**EVIDENCE**

**CONCLUSIONS FOR CARDIOMETABOLIC RISK**

There is **limited evidence** of a statistical association between cannabis use and:

- Incidence of prostate cancer, cervical cancer, malignant gliomas, non-Hodgkin lymphoma, penile cancer, anal cancer, Kaposi’s sarcoma, or bladder cancer
- Subsequent risk of developing acute myeloid leukemia/acute non-lymphoblastic leukemia, acute lymphoblastic leukemia, rhabdomyosarcoma, astrocytoma, or neuroblastoma in offspring (parental cannabis use)

<table>
<thead>
<tr>
<th>Evidence to support or refute a statistical association between cannabis use and:</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Incidence of prostate cancer, cervical cancer, malignant gliomas, non-Hodgkin lymphoma, penile cancer, anal cancer, Kaposi’s sarcoma, or bladder cancer • Subsequent risk of developing acute myeloid leukemia/acute non-lymphoblastic leukemia, acute lymphoblastic leukemia, rhabdomyosarcoma, astrocytoma, or neuroblastoma in offspring (parental cannabis use)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Evidence</th>
<th>Conclusions for Cardiometabolic Risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>limited evidence</strong> of a statistical association between cannabis use and:</td>
<td>• The triggering of acute myocardial infarction (cannabis smoking) • Ischemic stroke or subarachnoid hemorrhage • Decreased risk of metabolic syndrome and diabetes • Increased risk of prediabetes</td>
</tr>
<tr>
<td>There is <strong>no evidence</strong> to support or refute a statistical association between <strong>chronic effects</strong> of cannabis use and:</td>
<td>• The increased risk of acute myocardial infarction</td>
</tr>
</tbody>
</table>

**EVIDENCE**

**CONCLUSIONS FOR RESPIRATORY DISEASE**

There is **substantial evidence** of a statistical association between cannabis smoking and:

• Worse respiratory symptoms and more frequent chronic bronchitis episodes (long-term cannabis smoking)

<table>
<thead>
<tr>
<th>Evidence</th>
<th>Conclusions for Respiratory Disease</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>substantial evidence</strong> of a statistical association between cannabis smoking and:</td>
<td>• Improved airway dynamics with acute use, but not with chronic use • Higher forced vital capacity (FVC)</td>
</tr>
<tr>
<td>There is <strong>moderate evidence</strong> of a statistical association between cannabis smoking and:</td>
<td>• Improvements in respiratory symptoms.</td>
</tr>
<tr>
<td>There is <strong>limited evidence</strong> of a statistical association between cannabis smoking and:</td>
<td>• An increased risk of developing chronic obstructive pulmonary disease (COPD) when controlled for tobacco use (occasional cannabis smoking)</td>
</tr>
<tr>
<td>There is <strong>no or insufficient evidence</strong> to support or refute a statistical association between cannabis smoking and:</td>
<td>• Hospital admissions for COPD • Asthma development or asthma exacerbation</td>
</tr>
</tbody>
</table>

**EVIDENCE**

**CONCLUSIONS FOR IMMUNITY**

There is **limited evidence** of a statistical association between cannabis smoking and:

• A decrease in the production of several inflammatory cytokines in healthy individuals

<table>
<thead>
<tr>
<th>Evidence</th>
<th>Conclusions for Immunity</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>limited evidence</strong> of a statistical association between cannabis smoking and:</td>
<td>• The progression of liver fibrosis or hepatic disease in individuals with viral hepatitis C (HCV) (daily cannabis use)</td>
</tr>
<tr>
<td>There is <strong>limited evidence</strong> of no statistical association between cannabis use and:</td>
<td>• Other adverse immune cell responses in healthy individuals (cannabis smoking) • Adverse effects on immune status in individuals with HIV(cannabis or dronabinol use) • Increased incidence of oral human papilloma virus (HPV) (regular cannabis use)</td>
</tr>
<tr>
<td>There is <strong>no or insufficient evidence</strong> to support or refute a statistical association between cannabis use and:</td>
<td>• Increased risk of motor vehicle crashes</td>
</tr>
</tbody>
</table>

**EVIDENCE**

**CONCLUSIONS FOR INJURY AND DEATH**

There is **substantial evidence** of a statistical association between cannabis use and:

• Increased risk of motor vehicle crashes

<table>
<thead>
<tr>
<th>Evidence</th>
<th>Conclusions for Injury and Death</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>substantial evidence</strong> of a statistical association between cannabis use and:</td>
<td>• Increased risk of overdose injuries, including respiratory distress, among pediatric populations in U.S. states where cannabis is legal</td>
</tr>
<tr>
<td>There is <strong>moderate evidence</strong> of a statistical association between cannabis use and:</td>
<td>• All-cause mortality (self-reported cannabis use) • Occupational accidents or injuries (general, nonmedical cannabis use) • Death due to cannabis overdose</td>
</tr>
<tr>
<td>There is <strong>no or insufficient evidence</strong> to support or refute a statistical association between cannabis use and:</td>
<td>• All-cause mortality (self-reported cannabis use) • Occupational accidents or injuries (general, nonmedical cannabis use) • Death due to cannabis overdose</td>
</tr>
<tr>
<td>EVIDENCE</td>
<td>CONCLUSIONS FOR PREGNATAL, PERINATAL, AND NEONATAL EXPOSURE</td>
</tr>
<tr>
<td>-------------------------------------------------------------------------</td>
<td>-------------------------------------------------------------</td>
</tr>
<tr>
<td>There is <strong>substantial evidence</strong> of a statistical association between maternal cannabis smoking and:</td>
<td>• Lower birth weight of the offspring</td>
</tr>
<tr>
<td>There is <strong>limited evidence</strong> of a statistical association between maternal cannabis smoking and:</td>
<td>• Pregnancy complications for the mother</td>
</tr>
<tr>
<td>• Admission of the infant to the neonatal intensive care unit (NICU)</td>
<td></td>
</tr>
<tr>
<td>There is <strong>insufficient evidence</strong> to support or refute a statistical association between maternal cannabis smoking and:</td>
<td>• Later outcomes in the offspring (e.g., sudden infant death syndrome, cognition/academic achievement, and later substance use)</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EVIDENCE</th>
<th>CONCLUSIONS FOR PSYCHOSOCIAL</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>moderate evidence</strong> of a statistical association between cannabis use and:</td>
<td>• The impairment in the cognitive domains of learning, memory, and attention (acute cannabis use)</td>
</tr>
<tr>
<td>There is <strong>limited evidence</strong> of a statistical association between cannabis use and:</td>
<td>• Impaired academic achievement and education outcomes</td>
</tr>
<tr>
<td>• Increased rates of unemployment and/or low income</td>
<td>• Impaired social functioning or engagement in developmentally appropriate social roles</td>
</tr>
<tr>
<td>There is <strong>limited evidence</strong> of a statistical association between <strong>sustained abstinence from</strong> cannabis use and:</td>
<td>• Impairments in the cognitive domains of learning, memory, and attention</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EVIDENCE</th>
<th>CONCLUSIONS FOR MENTAL HEALTH</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>substantial evidence</strong> of a statistical association between cannabis use and:</td>
<td>• The development of schizophrenia or other psychoses, with the highest risk among the most frequent users</td>
</tr>
<tr>
<td>There is <strong>moderate evidence</strong> of a statistical association between cannabis use and:</td>
<td>• Better cognitive performance among individuals with psychotic disorders and a history of cannabis use</td>
</tr>
<tr>
<td>• Increased symptoms of mania and hypomania in individuals diagnosed with bipolar disorders (regular cannabis use)</td>
<td>• A small increased risk for the development of depressive disorders</td>
</tr>
<tr>
<td>• Increased incidence of suicidal ideation and suicide attempts with a higher incidence among heavier users</td>
<td>• Increased incidence of suicide completion</td>
</tr>
<tr>
<td>• Increased incidence of suicide completion</td>
<td>• Increased incidence of social anxiety disorder (regular cannabis use)</td>
</tr>
<tr>
<td>There is <strong>moderate evidence</strong> of <strong>no statistical association between</strong> cannabis use and:</td>
<td>• Worsening of negative symptoms of schizophrenia (e.g., blunted affect) among individuals with psychotic disorders</td>
</tr>
<tr>
<td>There is <strong>limited evidence</strong> of a statistical association between cannabis use and:</td>
<td>• An increase in positive symptoms of schizophrenia (e.g., hallucinations) among individuals with psychotic disorders</td>
</tr>
<tr>
<td>• The likelihood of developing bipolar disorder, particularly among regular or daily users</td>
<td>• The development of any type of anxiety disorder, except social anxiety disorder</td>
</tr>
<tr>
<td>• The development of any type of anxiety disorder</td>
<td>• Increased symptoms of anxiety (near daily cannabis use)</td>
</tr>
<tr>
<td>• Increased severity of posttraumatic stress disorder symptoms among individuals with posttraumatic stress disorder</td>
<td>• Increased severity of posttraumatic stress disorder symptoms among individuals with posttraumatic stress disorder</td>
</tr>
<tr>
<td>There is <strong>no evidence</strong> to support or refute a statistical association between cannabis use and:</td>
<td>• Changes in the course or symptoms of depressive disorders</td>
</tr>
<tr>
<td>• The development of posttraumatic stress disorder</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>EVIDENCE</th>
<th>CONCLUSIONS FOR PROBLEM CANNABIS USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>There is <strong>substantial evidence</strong> that:</td>
<td>• Stimulant treatment of attention deficit hyperactivity disorder (ADHD) during adolescence is <em>not</em> a risk factor for the development of problem cannabis use</td>
</tr>
</tbody>
</table>
• Being male and smoking cigarettes are risk factors for the progression of cannabis use to problem cannabis use
• Initiating cannabis use at an earlier age is a risk factor for the development of problem cannabis use

There is **substantial evidence** of a statistical association between:
• Increases in cannabis use frequency and the progression to developing problem cannabis use
• Being male and the severity of problem cannabis use, but the recurrence of problem cannabis use does not differ between males and females

There is **moderate evidence** that:
• Anxiety, personality disorders, and bipolar disorders are *not* risk factors for the development of problem cannabis use
• Major depressive disorder is a risk factor for the development of problem cannabis use
• Adolescent ADHD is *not* a risk factor for the development of problem cannabis use
• Being male is a risk factor for the development of problem cannabis use
• Exposure to the combined use of abused drugs is a risk factor for the development of problem cannabis use
• Neither alcohol nor nicotine dependence alone are risk factors for the progression from cannabis use to problem cannabis use
• During adolescence the frequency of cannabis use, oppositional behaviors, a younger age of first alcohol use, nicotine use, parental substance use, poor school performance, antisocial behaviors, and childhood sexual abuse are risk factors for the development of problem cannabis use

There is **moderate evidence** of a statistical association between:
• A persistence of problem cannabis use and a history of psychiatric treatment
• Problem cannabis use and increased severity of posttraumatic stress disorder symptoms

There is **limited evidence** that:
• Childhood anxiety and childhood depression are risk factors for the development of problem cannabis use

**EVIDENCE**

**CONCLUSIONS FOR CANNABIS USE AND THE ABUSE OF OTHER SUBSTANCES**

There is **moderate evidence** of a statistical association between cannabis use and:
• The development of substance dependence and/or a substance abuse disorder for substances, including alcohol, tobacco, and other illicit drugs

There is **limited evidence** of a statistical association between cannabis use and:
• The initiation of tobacco use
• Changes in the rates and use patterns of other licit and illicit substances

**EVIDENCE**

**CONCLUSIONS FOR CHALLENGES AND BARRIERS IN CONDUCTING CANNABIS RESEARCH**

There are several challenges and barriers in conducting cannabis and cannabinoid research, including:
• There are specific regulatory barriers, including the classification of cannabis as a Schedule I substance, that impede the advancement of cannabis and cannabinoid research
• It is often difficult for researchers to gain access to the quantity, quality, and type of cannabis product necessary to address specific research questions on the health effects of cannabis use
• A diverse network of funders is needed to support cannabis and cannabinoid research that explores the beneficial and harmful health effects of cannabis use
• To develop conclusive evidence for the effects of cannabis use on short- and long-term health outcomes, improvements and standardization in research methodology (including those used in controlled trials and observational studies) are needed
Whereas, Increased screen time amongst youth has been associated with an increase in morbidities such as obesity, sleep problems, depression and anxiety\(^1\); and

Whereas, Screen time can be utilized for both educational and recreational purposes; and

Whereas, Screens with artificial light, as found in smart phones and tablets, can emit a substantial amount of short-wavelength (blue-enriched) light emissions\(^2\); and

Whereas, The blue light emitted from screens can lead to disruption of circadian rhythm, as it suppresses melatonin secretion, and enhances alertness which can ultimately impact duration and quality of sleep\(^2,3\); therefore be it

RESOLVED, That our American Medical Association encourage all schools to incorporate into health class curriculum the topic of balancing screen time with physical activity and sleep (New HOD Policy); and be it further

RESOLVED, That the AMA encourage research into the utility of blue light filtering glasses and a blue light filter option on devices such as smart phones and tablets (New HOD Policy); and be it further

RESOLVED, That our AMA encourage physicians to assess all patients and educate all parents about amount of screen time, physical activity and sleep habits. (New HOD Policy)

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

Received: 09/06/17

References:
\(^2\) [http://www.health.harvard.edu/staying-healthy/blue-light-has-a-dark-side](http://www.health.harvard.edu/staying-healthy/blue-light-has-a-dark-side)

RELEVANT AMA POLICY

Human and Environmental Effects of Light Emitting Diode (LED) Community Lighting H-135.927
1. Our AMA supports the proper conversion to community-based Light Emitting Diode (LED) lighting, which reduces energy consumption and decreases the use of fossil fuels.
2. Our AMA encourages minimizing and controlling blue-rich environmental lighting by using the lowest emission of blue light possible to reduce glare.
3. Our AMA encourages the use of 3000K or lower lighting for outdoor installations such as roadways. All LED lighting should be properly shielded to minimize glare and detrimental human and environmental effects, and consideration should be given to utilize the ability of LED lighting to be dimmed for off-peak time periods. (CSAPH Rep. 02, A-16)
Whereas, Trichomoniasis is the most common curable sexually transmitted infection (STI) in the United States according to the Centers for Disease Control and Prevention (CDC) and the most common non-viral sexually transmitted infection (STI) in the world according to the World Health Organization,\(^1,2\) with a rate of reinfection increasing to 31% among women treated for *Trichomonas vaginalis*;\(^3,4\) and

Whereas, Trichomoniasis is not a reportable STI and “partner notification programmes are not available in most clinic settings”;\(^5,6\) and

Whereas, The most recent CDC 2015 STD treatment guidelines state, “concurrent treatment of all sex partners is critical for symptomatic relief, microbiologic cure, and prevention of transmission and reinfections, […] EPT might have a role in partner management for Trichomoniasis and can be used in states where permissible by law”;\(^7\) and

Whereas, Metronidazole is an effective, curative, easy, and safe treatment for *Trichomonas vaginalis* with recommended regimens yielding cure rates of approximately 84%–98%, and expedited partner therapy has been shown to decrease rates of reinfection;\(^8\) and

Whereas, Current AMA policy already supports state legislation that permits physicians to provide partner therapy for gonorrhea and/or chlamydia infections, both of which are less common than Trichomoniasis (AMA Policy H-440.868); and

Whereas, Expedited partner therapy potentially abrogates the standard informed consent process (Ethical Opinion E-8.9, “Expedited Partner Therapy”), and appropriate use of this therapy ultimately improves public health through management of sexually transmitted diseases; therefore be it

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\(^7\) CDC. Sexually Transmitted Diseases Treatment Guidelines, 2015. MMWR, 64(RR-03):1-137. [https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6403a1.htm](https://www.cdc.gov/mmwr/preview/mmwrhtml/rr6403a1.htm)

RESOLVED, That our American Medical Association amend policy H-440.868 by addition and deletion to read as follows:

H-440.868 Expedited Partner Therapy
Our AMA supports state legislation that permits physicians to provide expedited partner therapy to patients diagnosed with gonorrhea, and/or chlamydia, and/or Trichomoniasis infection. (Modify Current HOD Policy)

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

Received: 09/12/17

RELEVANT AMA POLICY

H-440.868 Expedited Partner Therapy
Our AMA supports state legislation that permits physicians to provide expedited partner therapy to patients diagnosed with gonorrhea and/or chlamydia infection. Citation: Sub. Res. 928, I-07 Reaffirmed: CSAPH Rep. 01, A-17

H-440.979 Control of Sexually Transmitted Infections
The AMA urges increased efforts at all levels of organized medicine to bring sexually transmitted infections under control, through professional and public education, and support of the efforts of state Departments of Health, the Centers for Disease Control and Prevention, the National Institutes of Health, and other appropriate organizations. Citation: Res. 84, A-84 Reaffirmed by CLRPD Rep. 3 - I-94 Reaffirmation A-99 Modified and Reaffirmed: CSAPH Rep. 1, A-09 Reaffirmation A-10

See also: H-440.983 Update on Sexually Transmitted Infections; H-440.996 Sexually Transmitted Disease Control; E-8.9 Expedited Partner Therapy
Whereas, Nearly 3 in 10 women and 1 in 10 men in America have experienced some form of intimate partner violence, including rape, physical violence, and/or stalking;¹ and

Whereas, Victims of violence by an intimate partner report issues such as fearing injury, the perpetrator limiting the victim’s access to money or social support, or needing resources such as medical care, legal services, housing services, victim’s advocate services, and/or crisis hotlines;¹ and

Whereas, Our AMA has not updated its Diagnostic and Treatment Guidelines on Domestic Violence since 1992, and since, research has shown that relationship violence in couples involving a transgender or otherwise identifying individual present unique circumstances²; and

Whereas, Violence against LGBT individuals, including domestic violence, is underreported and at times falsely attributed to other kinds of violence like hate crimes;³,⁴ and

Whereas, Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Others (LGTQ+) individuals who are victims of domestic violence may have an added pressure of staying in the relationship and/or seeking treatment out of fear of being outed to family members, friends, or employers;⁵,⁶,⁷ and

Whereas, Some transgender individuals may be pressured to stay in an abusive relationship due to their partner’s threats of limiting access to sex replacement hormones or otherwise exploiting their vulnerabilities with gender transitioning;⁸,⁹ and

Whereas, Some transgender victims of domestic violence avoid reporting their abuse or seeking treatment because they do not want to add to stigma against the transgender community;\(^9\) and

Whereas, Our AMA has committed to address health disparities in LGBT populations and has committed to address family and intimate partner violence (AMA PoliciesH-65.976, H-515.965); and

Whereas, The term Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Others (LGBTQ+) is an umbrella term for individuals whose gender identities and sexual orientations differ from those who are cisgender and heterosexual, and should be considered as an effort to be more inclusive than other acronyms like LGB, LGBT, etc. which may be present in some research throughout this resolution;\(^{10}\) therefore be it

RESOLVED, That our American Medical Association publish an update to its 1992 Diagnostic and Treatment Guidelines on Domestic Violence to reflect recent data and to address unique issues faced by the LGBTQ+ population (Directive to Take Action); and be it further

RESOLVED, That our AMA promote crisis resources for LGBTQ+ patients that cater to the specific needs of LGBTQ+ victims of domestic violence (New HOD Policy); and be it further

RESOLVED, That our AMA amend AMA Policy H-65.976 by addition to read as follows:

Nondiscriminatory Policy for the Health Care Needs of LGBTQ+ Populations H-65.976

Our AMA encourages physician practices, medical schools, hospitals, and clinics to broaden any nondiscriminatory statement made to patients, healthcare workers, or employees to include "sexual orientation, sex, or gender identity" in any nondiscrimination statement (Modify Current HOD Policy); and be it further

RESOLVED, That our AMA amend AMA policy H-160.991 by addition and deletion to read as follows:

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

1. Our AMA: (a) believes that the physician's nonjudgmental recognition of patients' sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian, gay, bisexual, transgender, queer/questioning, and other (LGBTQ+) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBTQ+; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBTQ+ Health and the need to elicit relevant gender and sexuality information from our patients; these efforts should start in medical school, but must also be a part of continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBTQ+ patients; (iii) encouraging the development of educational programs in LGBTQ+ Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBTQ+ people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBTQ+ communities to offer physicians the opportunity to better understand the medical needs of LGBTQ+ patients; and (c) opposes, the use of "reparative" or "conversion" therapy for sexual orientation or gender identity.


2. Our AMA will collaborate with our partner organizations to educate physicians regarding:

(i) the need for women who have sex with women to undergo regular cancer and sexually transmitted infection screenings due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; and (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases; and (iv) that individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, queer/questioning individuals) experience intimate partner violence, and how sexual and gender minorities present with intimate partner violence differs from their cisgender, heterosexual peers and may have unique complicating factors.

3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBTQ+ health issues.

4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBTQ+ people. (Modify Current HOD Policy)

Fiscal Note: Estimated cost of $85,500 to implement resolution.

Received: 09/12/17

RELEVANT AMA POLICY

Education of Medical Students and Residents about Domestic Violence Screening H-295.912
Family and Intimate Partner Violence H-515.965
Nondiscriminatory Policy for the Health Care Needs of LGBT Populations H-65.976
Whereas, Cervical cancer screening is indicated for female-to-male transgender patients who have a cervix and are sexually active, according to general cervical screening guidelines;¹ and

Whereas, Routine cervical screening has been shown to greatly reduce both the incidence of new cervical cancers diagnosed each year and deaths from the disease;²,³,⁴ and

Whereas, Some health care providers employ a misconception that female-to-male transgender patients have a lower risk of cervical cancer;⁵ and

Whereas, A recent survey of obstetricians and gynecologists found that only 29% were comfortable caring for female-to-male transgender patients;⁶ and

Whereas, Female-to-male transgender patients are significantly less likely to be up to date on Pap smears than cisgender women;⁷ and

Whereas, Female-to-male transgender patients face barriers to adequate cervical cancer screening, including lack of access to safe and inclusive health care providers and lack of education on the importance of continuing to receive Pap smears as compared to cisgender patients facing cervical cancer screenings;⁸,⁹,¹⁰,¹¹ and

Whereas, Even when receiving Pap smears, female-to-male transgender patients are significantly more likely to have longer periods to test follow up from ambiguous lab results than non-transgender patients; therefore be it RESOLVED, That our American Medical Association amend Policy H-160.991[2] by addition to read as follows:

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

2. Our AMA will collaborate with our partner organizations to educate physicians regarding:
   (i) the need for women who have sex with women and female-to-male transgender patients when medically indicated to undergo regular cancer and sexually transmitted infection screenings due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; and (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases. (Modify Current HOD Policy)

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

Received: 09/12/17

RELEVANT AMA POLICY

Health Care Needs of Lesbian Gay Bisexual and Transgender Populations H-160.991
1. Our AMA: (a) believes that the physician's nonjudgmental recognition of patients' sexual orientations, sexual behaviors, and gender identities enhances the ability to render optimal patient care in health as well as in illness. In the case of lesbian gay bisexual and transgender (LGBT) patients, this recognition is especially important to address the specific health care needs of people who are or may be LGBT; (b) is committed to taking a leadership role in: (i) educating physicians on the current state of research in and knowledge of LGBT Health and the need to elicit relevant gender and sexuality information from our patients; these efforts should start in medical school, but must also be a part of continuing medical education; (ii) educating physicians to recognize the physical and psychological needs of LGBT patients; (iii) encouraging the development of educational programs in LGBT Health; (iv) encouraging physicians to seek out local or national experts in the health care needs of LGBT people so that all physicians will achieve a better understanding of the medical needs of these populations; and (v) working with LGBT communities to offer physicians the opportunity to better understand the medical needs of LGBT patients; and (c) opposes, the use of "reparative" or "conversion" therapy for sexual orientation or gender identity.
2. Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for women who have sex with women to undergo regular cancer and sexually transmitted infection screenings due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; and (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases.
3. Our AMA will continue to work alongside our partner organizations, including GLMA, to increase physician competency on LGBT health issues.
4. Our AMA will continue to explore opportunities to collaborate with other organizations, focusing on issues of mutual concern in order to provide the most comprehensive and up-to-date education and information to enable the provision of high quality and culturally competent care to LGBT people.


See also: HPV Vaccine and Cervical Cancer Prevention Worldwide H-440.872
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 905
(I-17)

Introduced by: Medical Student Section

Subject: Addressing Social Media Usage and its Negative Impacts on Mental Health

Referred to: Reference Committee K
(L. Samuel Wann, MD, Chair)

Whereas, 71% of American teenagers use Facebook, 52% use Instagram, 41% use Snapchat, 24% of teens "go online almost constantly", and 92% go online every day;¹ and

Whereas, 68% of all US adults use Facebook, with 76% of them saying they check it daily;² and

Whereas, Several recent studies indicate a link between increased use of social media and higher levels of anxiety and depression;³,⁴,⁵,⁶ and

Whereas, The American Academy of Pediatrics recognizes depression that develops when preteens and teens spend a great deal of time on social media sites, and advises parents to talk to their children and adolescents about their online use;⁷ and

Whereas, There are school-based mental health programs that have evidence of positive impact across a range of emotional and behavioral problems; however, there are few programs that address the association between social media usage and negative mental health sequelae;⁸,⁹ therefore be it

RESOLVED, That our American Medical Association collaborate with relevant professional organizations to (a) develop continuing education programs to enhance physicians’ knowledge of the health impacts of social media usage, and (b) develop effective clinical tools and protocols for the identification, treatment, and referral of children, adolescents, and adults at risk for and experiencing mental health sequelae of social media usage (Directive to Take Action); and be it further

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RESOLVED, That our AMA advocate for schools to provide safe and effective educational programs by which students can learn to identify and mitigate the onset of mental health sequelae of social media usage. (New HOD Policy)

Fiscal Note: Estimated cost to implement resolution is $375,000.

Received: 09/12/17

RELEVANT AMA POLICY

Reduction of Online Bullying H-515.959

Internet Pornography: Protecting Children and Youth Who Use the Internet and Social Media H-60.934

Bullying Behaviors Among Children and Adolescents H-60.943

Providing Medical Services through School-Based Health Programs H-60.991

Awareness, Diagnosis and Treatment of Depression and other Mental Illnesses H-345.984

Increasing Detection of Mental Illness and Encouraging Education D-345.994
Whereas, Neonatal Abstinence Syndrome (NAS) is defined as a group of health problems seen in newborns exposed to addictive opiate drugs in utero, including dependency of the newborn\(^1\); and

Whereas, The National Institute on Drug Abuse found that the average hospital stay for an infant born with NAS is 16.9 days as opposed to the 2.1 day average of non NAS infants, leading to an extra $1.5 billion in hospital expenses in the year 2012\(^2\); which is a five-fold increase from 2000 to 2012; and

Whereas, Methadone and buprenorphine have been found to be effective and safe opioid maintenance therapies in pregnant and breastfeeding women\(^3\); with negligible amounts of methadone transmission in breast milk, and not a large enough amount of buprenorphine transmitted via breast milk to produce acute adverse effects\(^4,5\); and

Whereas, The benefits of breastfeeding with physician supervision has been found to supersede the risk of opioid exposure since it decreases the rate and severity of NAS in infants born to mothers undergoing opioid maintenance therapy\(^4,6\); and is advised by The American Society of Addiction Medicine\(^3\); and

Whereas, Seeking treatment for opioid addiction with the guidance of a physician is beneficial to newborn outcomes at any point during pregnancy and the AMA recognizes that breastfeeding is the optimal form of nutrition for breastfeeding infants (AMA Policy H-245.982);\(^7\); and

Whereas, Inadequate access to treatment for opioid addiction, limited options for medication-assisted programs during pregnancy and breastfeeding, lack of expertise among providers caring for opioid dependent pregnant and breastfeeding women and their opioid-exposed neonates, and insufficient resources to care for opioid-exposed neonates in low volume obstetric hospitals are challenges facing breastfeeding opioid dependent mothers, especially in rural and underserved communities;\(^8\); therefore be it

\(^1\) Neonatal abstinence syndrome: MedlinePlus Medical Encyclopedia. https://medlineplus.gov/ency/article/007313.htm
RESOLVED, That our American Medical Association’s Task Force to Reduce Opioid Abuse promote educational resources for opioid dependent mothers on the benefits and risks of breastfeeding while using opioid drugs or during maintenance therapy based on the most recent guidelines (New HOD Policy); and be it further

RESOLVED, That our AMA amend by addition existing AMA Policy H-420.962, “Perinatal Addiction - Issues in Care and Prevention,” to read as follows:

Perinatal Addiction - Issues in Care and Prevention H-420.962
Our AMA: (1) adopts the following statement: Transplacental drug transfer should not be subject to criminal sanctions or civil liability; (2) encourages the federal government to expand the proportion of funds allocated to drug treatment, prevention, and education. In particular, support is crucial for establishing and making broadly available specialized treatment programs for drug-addicted pregnant and breastfeeding women wherever possible; (3) urges the federal government to fund additional research to further knowledge about and effective treatment programs for drug-addicted pregnant and breastfeeding women, encourages also the support of research that provides long-term follow-up data on the developmental consequences of perinatal drug exposure, and identifies appropriate methodologies for early intervention with perinatally exposed children; (4) reaffirms the following statement: Pregnant and breastfeeding patients with substance use disorders should be provided with physician-led, team-based care that is evidence-based and offers the ancillary and supportive services that are necessary to support rehabilitation; and (5) through its communication vehicles, encourages all physicians to increase their knowledge regarding the effects of drug and alcohol use during pregnancy and breastfeeding and to routinely inquire about alcohol and drug use in the course of providing prenatal care. (Modify Current HOD Policy)

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

Received: 09/12/17

RELEVANT AMA POLICY

Perinatal Addiction- Issues in Care and Prevention H-420.962
Our AMA: (1) adopts the following statement: Transplacental drug transfer should not be subject to criminal sanctions or civil liability; (2) encourages the federal government to expand the proportion of funds allocated to drug treatment, prevention, and education. In particular, support is crucial for establishing and making broadly available specialized treatment programs for drug-addicted pregnant women wherever possible; (3) urges the federal government to fund additional research to further knowledge about and effective treatment programs for drug-addicted pregnant women, encourages also the support of research that provides long-term follow-up data on the developmental consequences of perinatal drug exposure, and identifies appropriate methodologies for early intervention with perinatally exposed children; (4) reaffirms the following statement: Pregnant and breastfeeding patients with substance use disorders should be provided with physician-led, team-based care that is evidence-based and offers the ancillary and supportive services that are necessary to support rehabilitation; and (5) through its communication vehicles, encourages all physicians to increase their knowledge regarding the effects of drug and alcohol use during pregnancy and breastfeeding and to routinely inquire about alcohol and drug use in the course of providing prenatal care. Citation: CSA Rep. G, A-92 Reaffirmation A-99 Reaffirmation A-09 Modified and Reaffirmed: CSAPH Rep. 1, A-09 Modified: Alt. Res. 507, A-16

See also: Education and Awareness of Opioid Pain Management Treatments, Including Responsible Use of Methadone D-120.985; Medical Direction of Methadone Treatment H-95.977; AMA Support for Breastfeeding H-245.982
Whereas, Over 420,000 children are within the foster care system according to the most recent data from the U.S. Department of Health & Human Services;¹ and

Whereas, A 2014 study indicates 48.3% of children within the foster care system experience four or more adverse family experiences, and these traumatic experiences lead to and include being removed from one’s home;² and

Whereas, Adults who had a history of being in the foster care system had significantly higher rates than the general population of post-traumatic stress disorder and toxic stress-related symptoms, such as attachment disorders, affect dysregulation, and behavior control issues;³ ⁴ and

Whereas, Toxic stress and childhood trauma can impact a child’s immune system, neurodevelopment, and genome resulting in delays in cognitive, behavioral, and physical development, in addition to leading to poor health outcomes into adulthood, such as alcoholism, chronic obstructive pulmonary disease, depression, cancer, obesity, increase in suicide attempts, and ischemic heart disease;³ ⁴ ⁵ ⁶ ⁷ ⁸ and

Whereas, Children within the foster system face unique legal and social barriers including limited healthcare records, difficulty in identifying who can consent to care for the child, court mandated treatments, and limited resources;⁹ ¹⁰ ¹¹ ¹² and

Whereas, Screenings, such as the Ages and Stages Questionnaire, can double the detection rate of developmental delay and lead to earlier intervention among children in foster care;¹³ and

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Whereas, The American Academy of Pediatrics identifies fifteen Models of Care which can be used for further creation of foster care clinics;\textsuperscript{14} and

Whereas, Existing foster care clinics, while limited in number, provide coordination of care, screenings regarding normal development, and transition support for the child and foster families;\textsuperscript{14,15} therefore be it

RESOLVED, That our American Medical Association advocate for comprehensive and evidence-based care that addresses the specific health care needs of foster care children. (New HOD Policy)

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

Received: 09/20/17

**RELEVANT AMA POLICY**

**Child Protection Legislation H-60.948**
**Promoting Physician Awareness of the Correlation Between Domestic Violence and Child Abuse D-515.982**


Whereas, Studies have demonstrated that conventional and unconventional methods of oil extraction, including acidization, vertical and horizontal drilling, and drilling in urban areas releases volatile organic compounds and heavy metals into local communities, including but not limited to methanol, ozone, crystalline silica, methanol, hydrochloric acid, formaldehyde, hydrofluoric acid, naphthalene, xylene, and ethylbenzene;¹,² and

Whereas, Naphthalene, methanol, formaldehyde, hydrochloric acid and hydrofluoric acid are associated with damage to multiple organ systems, including but not limited to the skin, eyes, and lungs, ozone increases smog production and the incidence of asthma, and chronic exposure to crystalline silica causes lung and autoimmune diseases;³,⁴,⁵,⁶ and

Whereas, Urban oil wells, drilling and refining facilities are often located close to residences, schools, hospitals, and religious institutions, especially in low income communities and communities of color;⁷,⁸,⁹ and

Whereas, Proximity to oil and gas development activities has been associated with reproductive abnormalities including congenital heart abnormalities, premature birth, high risk pregnancies, and low birth weight;¹⁰,¹¹,¹² and

Whereas, Individuals within one kilometer (3,280 feet) of well stimulation or other urban oil and gas development activities demonstrate higher rates of self-reported skin and respiratory symptoms including asthma, headache, nausea, epistaxis, experience greater ambient noise levels, and have a higher incidence of leukemia and a higher hazard index for chronic disease;¹³,¹⁴,¹⁵,¹⁶ and

⁵ McConnell, R. et al. Childhood Incident Asthma and Traffic-Related Air Pollution at Home and School. Environmental Health Perspectives; 2014, 118 (7): 1021–26
⁶ Bang, KM. et al. Silicosis mortality trends and new exposures to respirable crystalline silica--United States 2001-2010. CDC M&M Weekly Report; 2015, 64:5. Available at:
Whereas, Numerous states, cities, and towns have enacted buffer zones or setbacks ranging from 150 to 1,500 feet (45 to 407 meters) between well stimulation and sensitive public land uses, commissioned research into buffer zone distances, or banned drilling activities completely;\textsuperscript{17,18,19} therefore be it

RESOLVED, That our American Medical Association amend Policy H-135.949 by addition and deletion to read as follows:

**Support of Clean Air and Reduction in Power Plant Emissions H-135.949**

Our AMA supports (1) federal legislation and regulations that meaningfully reduce the following four major power plant emissions: mercury, carbon dioxide, sulfur dioxide and nitrogen oxide; and (2) efforts to limit carbon dioxide emissions through the reduction of the burning of coal in the nation's power generating plants, efforts to improve the efficiency of power plants, substitution of natural gas in lieu of other carbon-based fossil fuels, and continued development, promotion, and widespread implementation of alternative renewable energy sources in lieu of carbon-based fossil fuels. (Modify Current HOD Policy);

and be it further

RESOLVED, That our AMA support the implementation of buffer zones between oil and gas development sites and residences, schools, hospitals, and religious institutions. (New HOD Policy)

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

Received: 09/20/17

RELEVANT AMA POLICY

**Green Initiatives and the Health Care Community H-135.939**

Our AMA supports: (1) responsible waste management policies, including the promotion of appropriate recycling and waste reduction; (2) the use of ecologically sustainable products, foods, and materials when possible; (3) the development of products that are non-toxic, sustainable, and ecologically sound; (4) building practices that help reduce resource utilization and contribute to a healthy environment; and (5) community-wide adoption of 'green' initiatives and activities by organizations, businesses, homes, schools, and government and health care entities.


See also: Global Climate Change: The "Greenhouse Effect" (H-135.977); AMA Advocacy for Environmental Sustainability and Climate (H-135.923); Green Initiatives and the Health Care Community (H-135.939); The Health Risks of Hydraulic Fracturing (H-135.931); Environmental Health Programs (H-135.969); Stewardship of the Environment (H-135.973); Modern Chemicals Policies (H-135.942); Clean Air (H-135.991); Reducing Sources of Diesel Exhaust (D-135.996); The Need for Increased Research and Development in Nuclear Fusion to Reduce Environmental Pollution (H-460.956); Air Pollution and Public Health (H-135.941); Air Pollution and Public Health (D-135.985); Expense of Biohazardous Waste Removal (H-135.953); Pollution Control and Environmental Health (H-135.996); AMA Position on Air Pollution (H-135.998); Clean Air (H-135.979); Risks of Nuclear Energy and Low-Level Ionizing Radiation (H-455.994); Childhood Anaphylactic Reactions (D-60.976); Asthma Control (H-160.932); Protective NAAQS Standard for Fine Particulate Matter ((PM-2.5) (H-135.946)); Support the Health-Based Provisions of the Clean Air Act (H-135.950); Protective NAAQS Standard for Fine Particulate Matter ((PM-2.5) (D-135.983)); Protective NAAQS Standard for Particulate Matter ((PM 2.5 and PM 10) (D-135.978)); Support of Clean Air and Reduction in Power Plant Emissions (H-135.949); Federal Clean Air Legislation (H-135.984)

\textsuperscript{16}White, N. et al. Meteorologically estimated exposure but not distance predicts asthma symptoms in school children in the environs of a petrochemical refinery: a cross-sectional study. Environmental Health; 2009, 8:45.
\textsuperscript{17}McKenzie, L.M. et al. Human health risk assessment of air emissions from development of unconventional natural gas
Whereas, The opioid epidemic continues to ravage most of the nation; and
Whereas, Deaths from opioid overdose are rising; and
Whereas, Fentanyl and carfentanil are increasingly mixed with the heroin being sold by drug dealers, with an associated increased risk of fatal overdose; and
Whereas, The use of fentanyl and carfentanil increases the likelihood that the overdose state will return after successful revival with the first dose of naloxone; and
Whereas, The average opioid-addicted individual relapses multiple times and often overdoses multiple times before successful sobriety; and
Whereas, Individuals who have undergone the training program as laypersons typically receive only one dose of intranasal naloxone; and
Whereas, As opioid use grows, there is an increasing risk of overdoses occurring in crowded public areas and events; therefore be it

RESOLVED, That our American Medical Association study the practicality and utility of Naloxone rescue stations (public availability of Naloxone through wall-mounted display/storage units that also include instructions). (Directive to Take Action)

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

Received: 09/26/17
WHEREAS, At least one in seven women experience anxiety or depression during pregnancy or in the first year after birth, making mental health disorders the most common complication of pregnancy;\(^1\) and

WHEREAS, Despite the prevalence of anxiety and depression during pregnancy, maternal depression remains highly underdiagnosed and undertreated, with only 15 percent of women seeking professional evaluation for depressive symptoms (compared with 26% in the general population);\(^1\) and

WHEREAS, Growing evidence has demonstrated that maternal depression during the antenatal and postpartum periods increases the risk for many adverse outcomes among women and their children (including, poor cognitive outcomes in offspring and increased suicide rates among postpartum women);\(^2\),\(^3\) and

WHEREAS, There may be missed opportunities for screening women in an outpatient setting;\(^4\),\(^5\) and

WHEREAS, The American Congress of Obstetricians and Gynecologists recommends women be screened at least once for depression during pregnancy and once during the postnatal period;\(^4\),\(^5\) and

WHEREAS, The American Academy of Pediatrics (AAP) recommends pediatricians screen mothers for depression at well-baby visits during the first six months;\(^4\),\(^5\) and

WHEREAS, The AAP also recommends postpartum depression screening of mothers with low acuity complaints presenting to a pediatric emergency department with their child;\(^4\),\(^5\) and

WHEREAS, Many obstetricians or pediatricians, who are often at the frontline of diagnosis, lack training in responding to maternal mental-health concerns;\(^4\),\(^5\) and


Whereas, A statewide program called Massachusetts Child Psychiatry Access Program (MCPAP) for Moms provides a full-time consulting care coordinator available for pediatricians or other providers seeking advice on the appropriate treatment of a depressed pregnant or breastfeeding woman;⁶ and

Whereas, Treatments through MCPAP can include consultation with a perinatal psychiatrist, individual or group therapy geographically convenient for patients, medications, home visits by a nurse or social worker, or simply a follow-up phone call;⁶ therefore be it

RESOLVED, That our American Medical Association work with stakeholders to encourage the implementation of a routine protocol for depression screening in pregnant and postpartum women presenting alone or with their child during prenatal, postnatal, pediatric, or emergency room visits (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage the development of training materials related to maternal depression to advise providers on appropriate treatment and referral pathways (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage the development of state-based care coordination programs (e.g., staffing a psychiatrist and care coordinator) to assure appropriate referral, treatment and access to follow-up maternal mental health care. (Directive to Take Action)

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

Received: 09/28/17

RELEVANT AMA POLICY

Improving Mental Health Services for Pregnant and Postpartum Mothers H-420.953
Our AMA: (1) supports improvements in current mental health services for women during pregnancy and postpartum; (2) supports advocacy for inclusive insurance coverage of mental health services during gestation, and extension of postpartum mental health services coverage to one year postpartum; (3) supports appropriate organizations working to improve awareness and education among patients, families, and providers of the risks of mental illness during gestation and postpartum; and (4) will continue to advocate for funding programs that address perinatal and postpartum depression, anxiety and psychosis, and substance use disorder through research, public awareness, and support programs.
Citation: Res. 102, A-12; Modified: Res. 503, A-17

Access to Mental Health Services D-345.997
Our AMA will: (1) continue to work with relevant national medical specialty societies and other professional and patient advocacy groups to identify and eliminate barriers to access to treatment for mental illness, including barriers that disproportionately affect women and at-risk populations; (2) advocate that psychiatrists and other physicians who provide treatment for mental illness be paid by both private and public payers for the provision of evaluation and management services, for case management and coordination efforts, and for interpretive and indirect services; and (3) advocate that all insurance entities facilitate direct access to a psychiatrist in the referral process.
Citation: CMS Rep. 9, A-01; Reaffirmed: CMS Rep. 7, A-11; Reaffirmed in lieu of Res. 804, I-13; Reaffirmed in lieu of Res. 808, I-14; Modified: Res. 503, A-17

See also: Access to Mental Health Services H-345.981

Whereas, Pregnancy-related deaths doubled in the United States in the past 25 years;\(^1\) and

Whereas, An estimated 700 women die of pregnancy-related causes each year in the US and another 65,000 have serious health complications; many of these deaths and complications can be prevented\(^2\); and

Whereas, Leading causes of maternal deaths include cardiovascular disease, cardiomyopathy, thromboembolism, obstetric hemorrhage, preeclampsia, sepsis, hypertension and obesity, and more recently, drug overdose and maternal suicide;\(^3\) and

Whereas, The US lags far behind all other industrialized countries and is the only high-resource country with a rising maternal mortality rate;\(^4\) and

Whereas, There are significant and widening disparities in maternal mortality and morbidity, disproportionately impacting black women in the US;\(^5\) and

Whereas, There is a need to redouble efforts to prevent maternal deaths and national initiatives are underway to mobilize clinical and public health resources to improve safety in obstetric care, including establishing and strengthening state Maternal Mortality Review Committees; and

Whereas, The Centers for Disease Control and Prevention and ACOG recommend that all states have an active Maternal Mortality Review Committee; and

Whereas, Maternal Mortality Review Committees conduct systematic, confidential analysis of the medical and non-medical circumstances of deaths that occur during pregnancy or up to one year after--for the purpose of taking action to reduce the risk of women dying from complications of pregnancy; and

Whereas, Maternal Mortality Review Committees make specific, data-driven recommendations, identifying gaps in services and systems to prevent future deaths and near-misses as well as strengths in the systems of care that should be supported or expanded; and

\(^1\) Centers for Disease Control and Prevention. Trends in pregnancy related mortality. Available at: https://www.cdc.gov/reproductivehealth/maternalinfanthealth/pmss.html


Whereas, Review Committees conduct their confidential interviews and analysis of birth and death certificates, autopsy, hospital ER, medical transport, social services, and mental health records and reports within a culture of promoting safety—not to assign blame; and

Whereas, Maternal health and mortality are important indicators of the quality of health care and are at the core of what it means to have healthy, vibrant communities; therefore be it

RESOLVED, That our American Medical Association support the important work of maternal mortality review committees (New HOD Policy); and be it further

RESOLVED, That our AMA support work with state and specialty medical societies to advocate for state and federal legislation establishing Maternal Mortality Review Committees (New HOD Policy); and be it further

RESOLVED, That our AMA support work with state and specialty medical societies to secure funding from state and federal governments that fully supports the start-up and ongoing work of state Maternal Mortality Review Committees. (New HOD Policy)

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

Received: 10/05/17
Whereas, Smoking is the leading preventable cause of death, killing an estimated 480,000 persons in the United States and costing an estimated $325 billion in medical expenses and lost productivity each year; and

Whereas, If current trends continue, an estimated 5.6 million children in the United States alive today will ultimately die prematurely from smoking; and

Whereas, On August 17, 2006, a U.S. federal district court issued a 1,682 page final ruling in the case of United States v. Philip Morris concluding that Philip Morris, Altria, R.J. Reynolds, and other tobacco companies were in violation of the United States Racketeer Influenced and Corrupt Organizations (RICO) Act, noting that their goal has been “to make money with little, if any, regard for individual illness and suffering, soaring health costs, or the integrity of the legal system”; and

Whereas, To successfully prosecute defendants for a violation of the RICO Act, it must be proved that they have an ongoing pattern of criminal activity and the court found that “the evidence in this case clearly establishes that Defendants have not ceased engaging in unlawful activity...” and that “...their continuing conduct misleads consumers in order to maximize Defendants revenues by recruiting new smokers (the majority of whom are under the age of 18), preventing current smokers from quitting, and thereby sustaining the industry”; and

Whereas, The tobacco companies were ordered to publish “corrective statements" regarding “(a) the adverse health effects of smoking; (b) the addictiveness of smoking and nicotine; (c) the lack of any significant health benefit from smoking ‘low tar,’ ‘light,’ ‘ultralight,’ ‘mild,’ and ‘natural,’ cigarettes; (d) defendants' manipulation of cigarette design and composition to ensure optimum nicotine delivery; and (e) the adverse health effects of exposure to secondhand smoke”; and

Whereas, On May 22, 2009, a three-judge panel of the U.S. Court of Appeals issued a unanimous opinion affirming many of the findings of the lower court and all 4,088 findings of fact outlined in the ruling; and

Whereas, On June 28, 2010, the U.S. Supreme Court refused to hear appeals in the RICO verdict against the tobacco companies, thereby allowing the racketeering verdict to stand; and

Whereas, On April 25, 2017, a three-judge panel of the U.S. Court of Appeals unanimously ordered that the tobacco companies publish corrective statements; and
Whereas, The corrective statements will finally be published, beginning in November, in major newspapers, advertised during primetime on such national television channels as NBC, CBS, ABC or other channels with comparable reach; printed on “onserts” affixed to cigarette packages, and placed on the tobacco companies’ websites; and

Whereas, In all 50 U.S. states, one or more of the tobacco companies found to be in violation of RICO have retained lobbyists to influence state lawmakers; and

Whereas, Public support is strong for lawmakers to reject potential tobacco industry influences, particularly meals, gifts, or campaign contributions from tobacco companies or their lobbyists; and

Whereas, A strong majority of Americans think lawmakers shouldn’t trust tobacco companies as much as they trust other companies and, further, that lawmakers shouldn’t trust tobacco company lobbyists to provide accurate information on tobacco issues; and

Whereas, When asked if a tobacco-related law was written or influenced by a tobacco company or a tobacco company lobbyist, very few Americans think lawmakers should “leave the law as it is” and a strong majority of Americans think lawmakers should either “revise the law” or “remove the law and start over”; and

Whereas, Internal tobacco industry documents reveal that that tobacco companies have written or heavily influenced tobacco-related public policies since at least 1967; and

Whereas, Interference by the tobacco industry in government policy-making is known to be an important reason for governments’ failure to adopt proven measures to reduce tobacco consumption; and

Whereas, There is strong public support for a wide range of public policies actively opposed by tobacco companies yet proven effective in reducing the harms of tobacco by preventing initiation of smoking among youth and/or encouraging cessation of smoking among current users; therefore be it

RESOLVED, That our American Medical Association collaborate with members, component societies, and other interested public health organizations such as the Campaign for Tobacco Free Kids, Truth Initiative, the American Cancer Society, the American Lung Association and the American Heart Association, to help educate the public and policymakers about the tobacco companies’ organized conspiracy to commit fraud leading to the federal court verdict finding them in violation of the Racketeer Influenced and Corrupt Organization Act (RICO) and resulting in the corrective statements as ordered by the U.S. Court of Appeals in United States vs. Philip Morris (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage our component societies to work with appropriate public health organizations in their states to help identify public policies that may have been directly or indirectly influenced by tobacco companies or their lobbyists and encourage lawmakers to remediate all such influences, to reject any potential tobacco industry influences in the future, and to formally censure the tobacco companies for their fraudulent and harmful behavior. (New HOD Policy)

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

Received: 10/08/17
Whereas, Consistent increases in the life expectancy of the population of a country are expected and considered an indication of effective public health systems and health care and socio-economic well-being; and

Whereas, Life expectancy for the U.S. population decreased by 0.1 year from 2014 (78.9 years) to 2015 (78.8 years), including a decrease of 0.2 years (76.5 years to 76.3 years) for males and a decrease of 0.1 years (81.3 years to 81.2 years) for females; and

Whereas, U.S. life expectancy is now lower than in most high-income countries and this gap is projected to increase, and

Whereas, Continuous decline in the age-adjusted death rate for the total population of a country is expected and considered a sign of public health progress, good health care, and socio-economic well-being; and

Whereas, From 2014 to 2015, the age-adjusted death rate for the total population rose significantly for the first time since 1999, increasing by 1.2%, with age-adjusted death rate increases for non-Hispanic white males, non-Hispanic white females, and non-Hispanic black males; and

Whereas, Between 1999 and 2014, premature mortality increased in white individuals and in American Indians and Alaska Natives, and given that the magnitude of annual mortality increases in the USA is extremely unusual in high-income countries, a rapid public health response is needed to avert further premature deaths; therefore be it

RESOLVED, That our American Medical Association raise awareness of the recent reversals in the improvement of overall death rates and life expectancy with the message that these new problems in the United States are different from all other developed countries and that these trends need to be reversed promptly (Directive to Take Action); and be it further

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RESOLVED, That our AMA call on the legislative and executive branches of the Federal Government to fund and carry out investigations into the causes of these very unusual decreases in life expectancy and increases in death rates in order to design multi-disciplinary interventions to reverse these troubling changes (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage state and local medical societies to raise awareness of the new problems of decreasing life expectancy and increasing population death rates as indicators of major public health problems and advocate for local investigation of the causes and remedies for these disturbing problems. (New HOD Policy)

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

Received: 10/12/17
Whereas, A number of medical conditions have been associated with exposures to environmental chemicals in utero or during early development; and

Whereas, Differentiating likely causal connections from coincidental associations or confounders is complex and prone to misrepresentation; and

Whereas, Budgetary concerns threaten current and ongoing pediatric toxicological education and consultation services; and

Whereas, Socioeconomically disadvantaged and other susceptible populations are more likely to bear the health burden of many chemical exposures; therefore be it

RESOLVED, That our American Medical Association support the mission of and ongoing funding of academically-based regional Pediatric Environmental Health Specialty Units (PEHSU) by the Agency for Toxic Substances and Disease Registry of the Centers for Disease Control and Prevention (ATSDR/CDC) and the Environmental Protection Agency (EPA) (New HOD Policy); and be it further

RESOLVED, That our AMA support educational and consultative activities of the PEHSU program with local pediatricians, medical toxicologists, obstetricians, and others providing care to pregnant patients (New HOD Policy); and be it further

RESOLVED, That our AMA encourage the continuing training of physicians specializing in pediatric environmental health. (New HOD Policy)

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

Received: 10/11/17
Whereas, Inequalities in determinants of health and health outcomes continue to exist, with the color of a patient’s skin determining, at least in part, the quality of their health care; and

Whereas, Some of these disparities are due to differential treatment and care by physicians; and

Whereas, An ever-increasing number of patients in the United States identify as a member of a minority group, including approximately 38% of the current population; and

Whereas, Recognition of implicit bias and training in diversity and inclusion may mitigate both intentional and unintentional disparities in the provision of care to minority patients; and

Whereas, Reducing disparities requires national leadership to coordinate thoughtful, intentional action by leaders at each medical school and residency training program; therefore be it

RESOLVED, That our American Medical Association: (1) actively support the development and implementation of training implicit bias, diversity and inclusion as a component of medical education in all medical schools and residency programs; (2) identify and publicize effective strategies for educating residents in all specialties about disparities in their fields according to race and ethnicity, with particular regard to access to care and health outcomes; and (3) support research to identify the most effective strategies for educating physicians on how to eliminate disparities in health outcomes according to race and ethnicity. (Directive to Take Action)
Our AMA will advocate for the tracking and reporting to interested stakeholders of demographic information.

Our AMA will recommend that medical school admissions committees use holistic assessments of admission criteria that support them as they move through college, medical school and residency programs.

Our AMA will create and support pipeline programs and encourage support services for URM college students that are underrepresented in medicine (URM), to healthcare careers.

Our AMA will create and support programs that introduce elementary through high school students, especially those from groups that are underrepresented in medicine, to healthcare careers.

Our AMA will provide on-line educational materials for its membership that address diversity issues in patient care and create a diverse physician population.

Our AMA will develop an internal education program for its members on the issues and possibilities involved in creating a diverse physician population.

Our AMA will encourage the Liaison Committee on Medical Education to assure that medical schools demonstrate compliance with its requirements for a diverse student body and faculty.

Our AMA will partner with key stakeholders (including but not limited to the Association of American Medical Colleges, Association of American Indian Physicians, Association of Native American Medical Students, We Are Healers, and the Indian Health Service) to study and report back by July 2018 on why enrollment in medical school for Native Americans is declining in spite of an overall substantial increase in medical school enrollment, and lastly to propose remedies to solve the problems identified in the AMA study.

Our AMA will take a leadership role in efforts to enhance diversity in the physician workforce, including engaging in broad-based efforts that involve partners within and beyond the medical profession and medical education community.

Our AMA will work to obtain full restoration and protection of federal Title VII funding, and similar state funding programs, for the Centers of Excellence Program, Health Careers Opportunity Program, Area Health Education Centers, and other programs that support physician training, recruitment, and retention in geographically-underserved areas.

Our AMA will create and support programs that introduce elementary through high school students, especially those from groups that are underrepresented in medicine (URM), to healthcare careers.

Our AMA will create and support pipeline programs and encourage support services for URM college students that will support them as they move through college, medical school and residency programs.

Our AMA will recommend that medical school admissions committees use holistic assessments of admission applicants that take into account the diversity of preparation and the variety of talents that applicants bring to their education.

Our AMA will advocate for the tracking and reporting to interested stakeholders of demographic information pertaining to URM status collected from Electronic Residency Application Service (ERAS) applications through the National Resident Matching Program (NRMP).

Our AMA will continue the research, advocacy, collaborative partnerships and other work that was initiated by the Commission to End Health Care Disparities.

See also: Reducing Racial and Ethnic Disparities in Health Care D-350.995, Diversity in the Physician Workforce and Access to Care D-200.982
Whereas, The process of board certification has a central role in self-regulation of physician quality standards; and

Whereas, Each specialty has established non-profit organizations to administer this required evaluation to obtain and maintain board certification; and

Whereas, These organizations charge fees for the examination process that averages $110.00/year for family medicine to $610.00 per year for colon-rectal surgery; and

Whereas, The physicians taking the examination incur other costs such as review courses, travel expenses, and lost wages from their current practice; and

Whereas, Physician reimbursement has declined for many and further complicates the process involved in the cost of taking the exam; and

Whereas, The cumulative net assets of the various certifying organizations as stated in the reference below, is excessive and totals more than 584 million dollars (JAMA, August 1, 2017, Volume 318, #5: pages 477-479); therefore be it

RESOLVED, That our American Medical Association request reductions in Maintenance of Certification examination fees so as to work towards a balanced/neutral budget of ABMS medical boards given their status as non-profit organizations. (Directive to Take Action)

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

Received: 09/18/17

The topic of this resolution is currently under study by the Council on Medical Education
Whereas, Approximately 70% of the determinants of health status can be traced to environmental, preventive and life-style factors that are influenced by both primary care - patient and public health - community interventions of physicians; and

Whereas, There is a shortage of expertise in both such specialties, especially in rural communities; and

Whereas, Although many primary care physicians serve as “health officers”, other non-physician (even non-health professional) individuals with limited public health knowledge and skills lead the public health community effort in most rural communities; and

Whereas, Many primary care physicians have expressed a desire to greatly expand their public health/population health capacities, competencies and community leadership involvement but are not in a position to leave their practices for long periods to obtain board eligibility in preventive medicine and public health; and

Whereas, Many of these physicians have expressed a willingness to obtain the requisite public health board competencies through alternate “experiential” preceptorships, short didactic courses and other arrangements, while still maintaining the integrity of their practice; and

Whereas, The development of such expertise would greatly improve public health leadership, competencies and performance in such communities while, also, increasing physician presence and influence in overall community health policy and activities; therefore be it

RESOLVED, That our American Medical Association study, with the participation of the appropriate educational and certifying entities, innovative approaches that could be developed and/or implemented to promote interested physicians to obtain board eligibility in preventive medicine/public health to strengthen public health leadership, especially in rural communities.

(Directive to Take Action)

Fiscal Note: Modest - between $1,000 - $5,000.
Resolved, That our American Medical Association advocate for the formation of an Electronic Residency Application Service (ERAS) Residency Application Bias Minimization Committee to examine the role of bias in the residency training selection process (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for the modification of the ERAS Residency Application to minimize its bias in accordance with the suggestions of the ERAS Residency Application Bias Minimization Committee. (Directive to Take Action)
References:

RELEVANT AMA POLICY

Gender-Based Questioning in Residency Interviews H-310.976
The AMA (1) opposes gender-based questioning during residency interviews in both public and private institutions for the purpose of sexual discrimination; (2) supports inclusion in the AMA Fellowship and Residency Interactive Database Access (FREIDA) system information on residency Family and Medical Leave policies; and (3) supports monitoring the Accreditation Council for Graduate Medical Education as it proposes changes to the "Common Requirements" and the "Institutional Requirements" of the "Essentials of Accredited Residencies," to ensure that there is no gender-based bias.

Eliminating Questions Regarding Marital Status, Dependents, Plans for Marriage or Children, Sexual Orientation, Gender Identity, Age, Race, National Origin and Religion During the Residency and Fellowship Application Process H-310.919
Our AMA:
1. opposes questioning residency or fellowship applicants regarding marital status, dependents, plans for marriage or children, sexual orientation, gender identity, age, race, national origin, and religion.
2. will work with the Accreditation Council for Graduate Medical Education, the National Residency Matching Program, and other interested parties to eliminate questioning about or discrimination based on marital and dependent status, future plans for marriage or children, sexual orientation, age, race, national origin, and religion during the residency and fellowship application process.
3. will continue to support efforts to enhance racial and ethnic diversity in medicine. Information regarding race and ethnicity may be voluntarily provided by residency and fellowship applicants.
Res. 307, A-09

Oppose Discrimination in Residency Selection Based on International Medical Graduate Status D-255.982
Our AMA:
1. Will request that the Accreditation Council for Graduate Medical Education include in the Institutional Requirements a requirement that will prohibit a program or an institution from having a blanket policy to not interview, rank or accept international medical graduate applicants.
2. Recognizes that the assessment of the individual international medical graduate residency and fellowship applicant should be based on his/her education and experience.
3. Will disseminate this new policy on opposition to discrimination in residency selection based on international medical graduate status to the graduate medical education community through AMA mechanisms.
Sub. Res. 305, A-08 Reaffirmation I-11

See also: Eliminating Religious Discrimination from Residency Programs H-310.923
Whereas, In order to practice clinical medicine in an unsupervised setting, all physicians (international medical graduates and domestic graduates) must be licensed by the medical licensing board of the state where they plan to practice; and

Whereas, International medical graduates (IMGs) must be certified by the Educational Commission for Foreign Medical Graduates (ECFMG) and must pass USMLE Steps 1, Step 2 CK and Step 2 CS; and

Whereas, When a physician receives ECFMG certification, he/she may apply for an ACGME accredited residency; and

Whereas, Many ECFMG-certified IMGs are waiting to get into a residency program, but are unable to obtain a residency due to the limited number of residency slots available; and

Whereas, A significant shortage of primary care physicians is predicted ranging between 8,700 and 43,100 physicians by 2030;¹ which will further impact the availability of physicians and health care providers to care for patients in underserved areas of the United States;² and

Whereas, The Florida State Medical Board has implemented policies and laws to allow hospitals to employ physicians who have limited medical licenses as “house physicians” to work under the direct supervision of a physician who has an active Florida medical license and provide care to patients³; therefore be it

RESOLVED, That our American Medical Association work with state legislators and other regulatory organizations to develop the category of “House Physicians” to help address the anticipated physician need and shortfall of available practitioners in underserved areas of the United States. (Directive to Take Action)

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

Received: 09/22/17

References:
Whereas, Current Accreditation Council for Graduate Medical Education (ACGME) guidelines state that accredited obstetrics and gynecology (OB-GYN) residencies are required to provide access to abortion training in their curriculum, which the American Congress of Obstetricians and Gynecologists (ACOG) recognizes is a necessary component of women’s health care; and

Whereas, ACGME requires that all programs be held to the same high standards; however, ACOG reports that programs differ widely in scope and types of training offered; and

Whereas, There are many institutional barriers to medical education surrounding abortion, including legislative, societal, and monetary, all of which contribute to the limited access to family planning training opportunities; and

Whereas, Many institutions do not provide equal access to abortion training during OB-GYN residency training, only 54 percent of OB-GYN residents from 161 programs noted routine integrated abortion training, and 16 percent reported that elective training was not available; and

Whereas, In a 10-year study of Ryan Residency programs—which offer enhanced, integrated family planning education in OB-GYN residencies—there was a demonstrated 97 percent improved competency in abortion and contraceptive care, but they only make up 32 percent of all US OB-GYN residency programs; and

Whereas, Offering comprehensive, integrated training in abortion and family planning has shown to improve residents’ competency and proficiency in abortion, counseling, miscarriage management, and other reproductive care; and

Whereas, ACOG supports expansion of abortion training, and the improvement and integration of abortion education throughout all levels of medical education; and

Whereas, AMA policy supports the opportunity for residents to learn or opt-out of pregnancy termination procedures and opposes program measures aimed to interfere with or restrict the availability of this training; and

Whereas, AMA policy maintains that basic skills and competencies be determined solely by the medical profession; therefore be it...
RESOLVED, That our American Medical Association encourage the Accreditation Council for Graduate Medical Education to better enforce compliance with the standardization of abortion training opportunities as per the American Congress of Obstetricians and Gynecologists’ recommendations. (Directive to Take Action)

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

Received: 09/29/17

RELEVANT AMA POLICY

Medical Training and Termination of Pregnancy H-295.923
The AMA supports the education of medical students, residents and young physicians about the need for physicians who provide termination of pregnancy services, the medical and public health importance of access to safe termination of pregnancy, and the medical, ethical, legal and psychological principles associated with termination of pregnancy, although observation of, attendance at, or any direct or indirect participation in an abortion should not be required. Further, the AMA supports the opportunity for residents to learn procedures for termination of pregnancy and opposes efforts to interfere with or restrict the availability of this training.

Residency Program Responsibility for Resident Education H-295.915
The AMA affirms that the basic skills and competencies for the practice of medicine and its specialties must be determined solely by the medical profession.
Citation: Res. 313, A-96; Reaffirmed: CME Rep. 2, A-06; Reaffirmed: CME Rep. 01, A-16;

1 Accreditation Council for Graduate Medical Education. "ACGME program requirements for graduate medical education in obstetrics and gynecology." (2013).
Whereas, The cellular biology, gene expression, and hormonal profile differs between sexes and genders, and influence the clinical presentation, progression, and outcome for a variety of diseases; and

Whereas, The Institute of Medicine supports the advent and implementation of sex and gender based medicine in daily practice of patient care due to its multifactorial impact on overall patient health and disease prognosis; and

Whereas, Sex and gender based medical education is a critical component in the pursuit of more personalized medicine; and

Whereas, The majority of current educational materials used in medical education have a gender-bias toward male patients, and educators must make the conscious decision to offer learning materials and teaching that is sex and gender based; and

Whereas, There are demonstrated sex and gender differences in drug responses to therapeutic doses due to variations in gene expression leading to increases in adverse effects disproportionately in the female sex; and

Whereas, Sex and gender-based medicine (SGBM) may not currently be addressed in undergraduate or graduate medical education, and medical students and residents may not fully understand the impact of these differences on patient care; and

Whereas, A recent study shows 96 percent of medical students are aware of differences in SGBM, and 94.2 percent believe including it in the curriculum improves their ability to care for future patients; and

Whereas, Some schools have already adapted their curriculum to include SGBM through integration into existing educational resources, including clinical cases and learning modules; and

Whereas, Over twenty national and international organizations and schools are already addressing sex and gender implications in medical education and continuing medical education curricula; and

Whereas, The AMA has recently expanded the definition of women’s health to be inclusive of all health conditions for which there is evidence that women’s risks, presentations, and/or responses to treatment are different from those of men, and encouraged physicians to use this in their training; and
Whereas, The AMA has previously resolved to encourage the research of sex and gender differences in medicine, and recommends that medical/scientific journals require sex based analysis of data when appropriate\textsuperscript{14}; therefore be it

RESOLVED, That our American Medical Association ask the AMA Council on Medical Education and Academic Physician Section to encourage the Accreditation Council for Graduate Medical Education, Liaison Committee on Medical Education, Commission on Osteopathic Accreditation, Association of American Medical Colleges, and Accreditation Council for Continuing Medical Education to assure the inclusion of sex and gender based medicine in medical education programs across the spectrum of learners nationwide. (Directive to Take Action)

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

Received: 09/29/17

RELEVANT AMA POLICY

An Expanded Definition of Women's Health H-525.976,

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

Citation: CSAPH Rep. 05, A-16;

See also: Medical Education and Training in Women's Health H-295.890, Sex and Gender Differences in Medical Research H-525.988

\textsuperscript{4} Pinn VW. Sex and Gender Factors in Medical Studies: Implications for Health and Clinical Practice. JAMA. 2003;289(4):397-400.
\textsuperscript{9} Jenkins, Marjorie R., Richard Dickerson, Michael Song, Chwan-Li Shen, Susan Bergeson, Betsy Jones, Simon Williams, Robert Casanova, Texas Tech University Health Sciences Center School of Medicine, and Laura W. Bush Institute for Women's Health. Direct Connection of Foundational Science Principles to Clinical Care. Texas Tech Sex and Gender-Based Medicine Longitudinal Curriculum Model. N.p., n.d. Web.
\textsuperscript{10} McGregor, Alyson J., Ana Nuñez, Rebecca Barron, Robert Casanova, and Eliza Lo Chin. "Workshop Summaries from the 2015 Sex and Gender Medical Education Summit: Utilization of Sex and Gender Based Medical Education Resources and Creating Student Competencies." Biology of Sex Differences. BioMed Central, 14 Oct. 2016. Web. 21 Feb. 2017
\textsuperscript{11} Sex and Gender Women's Health Collaborative – Collaborators (http://sgwhc.org/participate/collaborators/#tshelf.krbySyvku.dpbs)
\textsuperscript{13} AMA Resolution H-525.976. "An Expanded Definition of Women's Health". Approved 2016.
Whereas, Four healthy lifestyle factors—never smoking, maintaining a healthy weight, exercising regularly, and following a healthy diet—together appear to be associated with as much as an 80 percent reduction in the risk of developing the most common and deadly chronic diseases, such as cardiovascular disease, cancer, and diabetes; and

Whereas, The Bipartisan Policy Center has called for improving medical education and training in “topics such as nutrition and physical activity that have an important role to play in the prevention and treatment of obesity and chronic diseases,” since “these topics have traditionally received little attention in formal medical school curricula;” and

Whereas, Many physicians and other healthcare providers are not adequately trained in nutrition and physical activity and other lifestyle components in a way that could mitigate disease development and progression; and

Whereas, In a report from 2010, only 25% of medical schools surveyed required a dedicated nutrition course (down from 30% in 2004) and only 27% of schools surveyed met the minimum 25 required hours of nutrition instruction set by the National Academy of Sciences (down from 38% in 2004); and

Whereas, Patients advised to quit smoking by their physicians are 1.6 times more likely to quit than patients not receiving physician advice; however, most smokers do not receive this advice when visiting their physicians; and

Whereas, Just 34% of U.S. adults reported exercise counseling at their last medical visit; and

Whereas, In a study of internal medicine physicians, less than half reported confidence in knowledge of local exercise facilities, American College of Sports Medicine (ACSM) guidelines, and behavior modification techniques; therefore be it

RESOLVED, That our American Medical Association support legislation that incentivizes and/or provides funding for the inclusion of lifestyle medicine education in medical school education, graduate medical education, and continuing medical education, including but not limited to education in nutrition, physical activity, behavior change, sleep health, tobacco cessation, alcohol use reduction, emotional wellness, and stress reduction. (New HOD Policy)
RELEVANT AMA POLICY

Healthy Lifestyles H-425.972
Our AMA: (1) recognizes the 15 competencies of lifestyle medicine as defined by a blue ribbon panel of experts convened in 2009 whose consensus statement was published in the Journal of the American Medical Association in 2010; (2) will urge physicians to acquire and apply the 15 clinical competencies of lifestyle medicine, and offer evidence-based lifestyle interventions as the first and primary mode of preventing and, when appropriate, treating chronic disease within clinical medicine; and (3) will work with appropriate federal agencies, medical specialty societies, and public health organizations to educate and assist physicians to routinely address physical activity and nutrition, tobacco cessation and other lifestyle factors with their patients as the primary strategy for chronic disease prevention and management.

Citation: Res. 423, A-12

E-8.11 Health Promotion and Preventive Care

Medicine and public health share an ethical foundation stemming from the essential and direct role that health plays in human flourishing. While a physicians role tends to focus on diagnosing and treating illness once it occurs, physicians also have a professional commitment to prevent disease and promote health and well-being for their patients and the community.

The clinical encounter provides an opportunity for the physician to engage the patient in the process of health promotion. Effective elements of this process may include educating and motivating patients regarding healthy lifestyle, helping patients by assessing their needs, preferences, and readiness for change and recommending appropriate preventive care measures. Implementing effective health promotion practices is consistent with physicians duties to patients and also with their responsibilities as stewards of health care resources.

While primary care physicians are typically the patients main source for health promotion and disease prevention, specialists can play an important role, particularly when the specialist has a close or long-standing relationship with the patient or when recommended action is particularly relevant for the condition that the specialist is treating. Additionally, while all physicians must balance a commitment to individual patients with the health of the public, physicians who work solely or primarily in a public health capacity should uphold accepted standards of medical professionalism by implementing policies that appropriately balance individual liberties with the social goals of public health policies.

Health promotion should be a collaborative, patient-centered process that promotes trust and recognizes patients self-directed roles and responsibilities in maintaining health. In keeping with their professional commitment to the health of patients and the public, physicians should:

(a) Keep current with preventive care guidelines that apply to their patients and ensure that the interventions they recommend are well supported by the best available evidence.
(b) Educate patients about relevant modifiable risk factors.
(c) Recommend and encourage patients to have appropriate vaccinations and screenings.
(d) Encourage an open dialogue regarding circumstances that may make it difficult to manage chronic conditions or maintain a healthy lifestyle, such as transportation, work and home environments, and social support systems.
(e) Collaborate with the patient to develop recommendations that are most likely to be effective.
(f) When appropriate, delegate health promotion activities to other professionals or other resources available in the community who can help counsel and educate patients.
(g) Consider the health of the community when treating their own patients and identify and notify public health authorities if and when they notice patterns in patient health that may indicate a health risk for others.
(h) Recognize that modeling health behaviors can help patients make changes in their own lives.

Collectively, physicians should:

(i) Promote training in health promotion and disease prevention during medical school, residency and in continuing medical education.
(j) Advocate for healthier schools, workplaces and communities.
(k) Create or promote healthier work and training environments for physicians.
(l) Advocate for community resources designed to promote health and provide access to preventive services.
(m) Support research to improve the evidence for disease prevention and health promotion.