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\* Contained in Handbook Addendum

# REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 1-I-19

Subject: Mandatory Reporting of Diseases and Conditions (Resolution 915-I-18)

Presented by: Michael M. Miller, MD, Chair

Referred to: Reference Committee K

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Resolution 915-I-18, introduced by the American College of Emergency Physicians and referred by the House of Delegates asks:

That our American Medical Association oppose mandated reporting of entire classes of patients and specific diagnoses unless compelling evidence exists to demonstrate that a serious public health and/or safety risk will be mitigated as a result of such reporting.

## METHODS

English language reports were selected from searches of the PubMed, Google Scholar, and Cochrane Library databases from January 2009 to August 2019 using the search terms: “mandatory reporting,” “nationally notifiable condition,” “electronic case reporting,” “public health surveillance,” “chronic disease registry,” “mandatory reporting” and “noncommunicable disease.” Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by federal agencies, applicable professional organizations, and foundations were also reviewed for relevant information.

## CURRENT AMA POLICY

The AMA has numerous policies calling for improved public health surveillance (e.g., antibiotic use and resistance, cannabis, Creutzfeldt-Jakob disease, firearm-related injuries and deaths, human immunodeficiency virus, infant mortality, lead poisoning, maternal mortality, new psychoactive substances, radon exposure, tobacco consumption, tuberculosis, vector-borne diseases, zoonotic diseases, etc). These policies do not address mandatory reporting or the burden of reporting on physicians. AMA policy also does not address the work underway to modernize public health surveillance and implement electronic case reporting (eCR) thereby removing the burden on physicians, labs, hospitals, and others required to report for the purposes of public health surveillance.

This report will define public health surveillance, explain the difference between mandatory reporting and nationally notifiable conditions, discuss the history of public health surveillance and its expansion beyond infectious diseases, and explain work underway to implement electronic case reporting (eCR) to both improve surveillance and alleviate the burden of reporting on those required to report. The Council on Science and Public Health recognizes public health surveillance is not without risks for individual participants and can pose ethical dilemmas. However, when conducted ethically, public health surveillance is justified for the common good to promote population health and reduce inequalities.<sup>1</sup> The ethical framework for conducting public health surveillance is outside the scope of this report.

## BACKGROUND

Public health surveillance is the ongoing systematic collection, analysis, interpretation and dissemination of health data for the planning, implementation and evaluation of public health action.<sup>2</sup> Public health surveillance is an essential public health function.<sup>3</sup> Surveillance data can be used to estimate the magnitude of health problems, determine the distribution of illness in a population, depict the natural history of a disease, generate hypotheses, stimulate research, evaluate control measures, monitor changes, and facilitate planning.<sup>4</sup>

Disease surveillance usually begins in the health care setting as public health agencies collect disease information from health care providers, facilities, and clinical laboratories required to report diseases and conditions to public health agencies.<sup>5</sup> In the United States, the authority to require notification of cases of diseases resides with the jurisdiction's state legislature.<sup>6</sup> As a result, the list of diseases and conditions that are reported varies by state.<sup>6</sup> In addition, the time frames for reporting, agencies receiving reports, persons required to report, and conditions under which reports are required also differ.<sup>6</sup> Traditionally, disease reports were made manually or by telephone, mail, or fax.<sup>5</sup> Reporters have indicated that manual submission of disease reports is time-consuming and disruptive to workflow.<sup>5</sup>

The Nationally Notifiable Disease List differs from mandatory reporting in that notifiable diseases are reported to the Centers for Disease Control and Prevention (CDC) on a voluntary basis by each jurisdiction. The Council of State and Territorial Epidemiologists works with the CDC to determine which conditions reported to local, state, and territorial public health departments are nationally notifiable.<sup>8</sup>

This Council on Science and Public Health report stems from the enactment of legislation in California in 2017 that requires the State Department of Public Health to collect data on the incidence of Parkinson's disease in California.<sup>8</sup> The legislation also requires a hospital, facility, physician and surgeon, or other health care provider diagnosing or providing treatment to Parkinson's disease patients to report each case of Parkinson's disease to the department, beginning July 1, 2018.<sup>8</sup>

## DISCUSSION

Historically, surveillance focused on infectious diseases, it then broadened to other topics, including chronic diseases (e.g., cancer and diabetes), occupational health, environmental health, hazard surveillance (toxic chemicals and physical and biological agents), and injury control (e.g., firearm-related injury).<sup>9</sup> It is expected that additional diseases and conditions will be explored in the future.<sup>9</sup> As state legislatures consider adding to their jurisdiction's list of diseases and conditions that are required to be reported to public health agencies, they should consult with state and national medical societies and public health agencies to ensure the requirements are based on scientific evidence and will meet the needs of population health.

### *Chronic Disease Surveillance*

Chronic diseases are conditions that last 1 year or more and require ongoing medical attention or limit activities of daily living or both. Chronic diseases such as heart disease, cancer, and diabetes are the leading causes of death and disability in the United States and the leading drivers of health care costs.<sup>10</sup> The rise in chronic disease burden led to the development of chronic disease surveillance systems. In the 1970s, morbidity from select chronic diseases came under surveillance through disease registries.<sup>11</sup> In the 1980s and 1990s, CDC and state health agencies

collaboratively developed additional surveillance systems to monitor behavioral risk factors for chronic disease.<sup>11</sup> This led to the use of the Behavioral Risk Factor Surveillance System and the Youth Risk Behavioral Surveillance System to monitor health risk behaviors.<sup>11</sup> In 1992, Congress authorized the National Program of Cancer Registries at CDC to monitor local trends in cancer incidence and mortality with statewide, population-based cancer registries.<sup>11</sup> The benefits of public health surveillance on these conditions include determining incidence and survival rates, evaluating treatment efficacy, targeting educational and screening programs, and conducting research on etiology, diagnosis and treatment.

#### *Neurological Conditions Surveillance*

In 2016, as part of the 21st Century Cures Act, Congress authorized CDC to initiate development of a National Neurological Conditions Surveillance System to begin collecting and analyzing data on neurological disorders.<sup>20</sup> The CDC will begin by exploring and synthesizing data from existing sources to gain an increased understanding of multiple sclerosis and Parkinson's disease.<sup>20</sup> Once model approaches for surveillance are identified, the NCSS will be extended to other neurological conditions as resources allow.<sup>20</sup>

On the state level, Nebraska was the first jurisdiction to implement a Parkinson's disease registry. The law requires that physicians and pharmacists report individuals diagnosed with Parkinson's and patients taking anti-Parkinson's medications to the Nebraska Department of Health and Human Services Regulation and Licensure.<sup>12</sup> In 2015, Utah launched its Parkinson's Disease Registry to understand the apparent rise in the disease in the state and uncover causes of the disease. Effective March 12, 2015, the Utah State Board of Health began requiring health care providers to report cases of Parkinson's Disease and related movement disorders.<sup>13</sup> California was the third state to require reporting of Parkinson's Disease. Since July of 2018, 122,727 records have been submitted to the California Parkinson's Disease Registry.<sup>14</sup> These data will be used to: (1) determine the incidence and prevalence of Parkinson's disease in California; (2) examine disparities in Parkinson's disease risk; and (3) conduct demographic and epidemiological research and other studies of Parkinson's disease.<sup>15</sup> These provisions under the California law are set to expire in 2020, but legislation is currently being considered to extend the registry and reporting requirements beyond 2020.

#### **DIGITAL BRIDGE**

The Digital Bridge, funded by the Robert Wood Johnson Foundation and the de Beaumont Foundation, provides a forum for key decision-makers in health care, public health and health information technology (IT) committed to promoting bidirectional, or two-way, information exchange between the health care and public health sectors.<sup>16</sup> The Digital Bridge promotes the use of national health IT infrastructure to alleviate the administrative burden and costs of outdated, siloed data exchange practices.<sup>16</sup> Goals for the Digital Bridge include: (1) easing the burden and costs for all stakeholder groups through a unified approach to information exchange; (2) advancing greater standards-based information exchange across public health and health care; and (3) laying the foundation for greater bidirectional exchange of data so that clinicians can be more informed about population health, environmental risks and outbreaks.<sup>16</sup> The AMA is currently a member of the Governance Body for the Digital Bridge. Electronic case reporting (eCR) was the first use case for the Digital Bridge.

## *Electronic Case Reporting (eCR)*

With more than 80 percent of office-based physicians having adopted electronic health record (EHR) systems, it is not surprising the future of public health surveillance is eCR, a process by which reportable conditions are automatically generated from EHR systems to public health agencies for review and action, in accordance with applicable health care privacy and public health reporting laws<sup>17</sup> (see Figure). The advancement of eCR could lead to more accurate and timely case data for public health action resulting in improved detection of outbreaks, earlier identification of disease risk factors, and a decreased burden on mandatory reporters, including physicians.<sup>17</sup>

The electronic initial case report (eICR) would be identified in the EHR through a standard set of trigger codes that flag when a provider diagnoses a reportable condition based on International Classification of Diseases, Tenth Revision codes for diagnoses, LOINC (Logical Observation Identifiers Names and Codes) for laboratory testing orders, or SNOMED CT (Systematized Nomenclature of Medicine–Clinical Terms) for clinical information and laboratory results.<sup>16</sup> The Association of Public Health Laboratories, Council of State and Territorial Epidemiologists, and CDC have already vetted the reportable trigger codes for 5 conditions (e.g., gonorrhea, chlamydia, salmonella, pertussis, and Zika virus infections) and are in the process of identifying codes for all reportable conditions.<sup>17</sup>

After potential cases are identified through trigger codes, the eICR will automatically be generated with case information.<sup>17</sup> The eICR will contain a minimum set of data elements that have been established to be used for all conditions in all jurisdictions. The eICR will be transmitted from the EHR to an intermediary platform via secure, broadly used data transport mechanisms.<sup>16</sup> On these platforms, a software application will assess the reportability of the disease or condition via a logic model based on the jurisdiction's mandated reporting requirements and then will route adjudicated cases to the appropriate agencies.<sup>17</sup>

The Reportable Conditions Knowledge Management System (RCKMS) is a software application that will unpack, transform, and adjudicate the eICR automatically in a secure environment to determine whether the potential case meets minimal criteria consistent with mandated reporting based on a standard logic specific to jurisdictional requirements. RCKMS will transmit reportable cases to jurisdictions for final classification and action.<sup>17</sup> Health care providers will be informed when cases have been reported.<sup>16</sup> CDC has supported the Health Level 7 Consolidated Clinical Document Architecture as the initial structure for transmitting the eICR, based on standards that are already in use.

Houston was the first pilot site under the Digital Bridge initiative to successfully launch eCR. Partners involved in the Houston demonstration include Houston Health Department, Houston Methodist, and Epic Systems.<sup>18</sup> California, Kansas, Massachusetts, Michigan, New York, and Utah have also been selected as pilot sites.<sup>19</sup> The CDC recently identified Parkinson's disease for inclusion as a test case for the Digital Bridge. The Digital Bridge and CDC have committed to working with the California Department of Public Health to implement eCR across California health systems to collect data on Parkinson's disease cases seen by health care providers in a burden-free manner.

## CONCLUSION

Public health surveillance is an essential public health function and coordination between health care and public health agencies is essential for the monitoring, control, and prevention of disease. The AMA has numerous policies calling for improved public health surveillance on a wide range

of topics. A policy opposing mandatory reporting for specific conditions due the burden it places on physicians could jeopardize our understanding of disease occurrence and severity (e.g., cancer), as well as new causes, risk factors, and early identification of disease clusters. In addition to increases in disease incidence, reporting can also demonstrate the decline in disease among the population and help with the evaluation of prevention programs (e.g., vaccines).

To ensure that new diseases reporting requirements are based on the scientific evidence and will meet the needs of population health, the AMA encourages state legislatures to engage state and national medical specialty societies and public health agencies when proposing mandatory disease reporting requirements. The AMA should also support the modernization of public health surveillance systems and recognize the benefits of eCR in both improving public health surveillance through more accurate and timely data and alleviating the reporting burden on physicians.

## RECOMMENDATIONS

The Council recommends that the following recommendation for new policy be adopted in lieu of Resolution 915-I-18, and the remainder of the report be filed.

### Public Health Surveillance

That our AMA: (1) recognizes public health surveillance as a core public health function that is essential to inform decision making, identify underlying causes and etiologies, and respond to acute, chronic, and emerging health threats; (2) recognizes the important role that physicians play in public health surveillance through reporting diseases and conditions to public health authorities; (3) encourages state legislatures to engage relevant state and national medical specialty societies as well as public health agencies when proposing mandatory reporting requirements to ensure they are based on scientific evidence and meet the needs of population health; (4) recognizes the need for increased federal funding to modernize our nation's public health data systems to improve the quality and timeliness of data; (5) supports electronic case reporting, which alleviates the burden of case reporting on physicians through the automatic generation and transmission of case reports from electronic health records to public health agencies for review and action in accordance with applicable health care privacy and public health reporting laws; (6) will share updates with physicians and medical societies on public health surveillance and the progress made toward implementing electronic case reporting.  
(New HOD Policy)

Fiscal Note: less than \$1,000.

Figure



Source: The Digital Bridge

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REPORT 2 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-19)  
Real-World Data and Real-World Evidence in Medical Product Decision Making  
(Reference Committee K)

EXECUTIVE SUMMARY

Objective. The Council on Science and Public Health initiated this report to inform physicians of the evolving use of real-world data (RWD) and real-world evidence (RWE) in medical product decision making, specifically how the U.S. Food and Drug Administration (FDA) is using RWD and RWE for the approval of new products, new indications for products, or new labeling on products that are used in patient care. This report will define and clarify the current working definition and types/sources of RWD and RWE, evaluate challenges and benefits in using RWD, provide examples of RWD platforms and use of RWE, and explore considerations for generating RWE that is fit for regulatory purposes.

Methods. English-language articles were selected from a search of the PubMed database through August 2018 using the search terms “real-world data” and “real-world evidence.” Due to the volume of results, the date range was limited to 2017 to present. Additional articles were identified from a review of the references cited in relevant, retrieved publications. Searches of websites of international and national government agencies and outcomes research organizations and associations were conducted to identify guidelines, position statements, and reports.

Results. Data is more widely collected, available, and accessible than in the past. Evidence and opportunities are mounting on ways to leverage new data sources such as RWD and RWE to support regulatory efforts and value-based payment arrangements for medical products, yet accessibility and privacy concerns remain. The FDA is actively engaged in understanding the potential of RWE to meet the established standards for adequate and well-controlled clinical investigations and pursuing its integration into drug development and regulatory review, the support of new indications for an approved drug, and its ability to satisfy post-approval study requirements. Advocates note that the use of RWD and RWE is crucial for incorporating patient experiences, currently often a gap in knowledge, into decision-making by drug companies, insurers, providers, and regulators. If RWD and RWE are to be effectively leveraged for public health purposes, then shared learning and collaboration across clinicians, patients, health care systems, pharmaceutical companies, and regulators are necessary. An understanding of the limitations and barriers associated with the use of RWD must also be acknowledged and addressed.

Conclusion. With its increasing availability and recognized worth, RWE has the potential to support, improve, and potentially accelerate the delivery of safe and cost-effective medical products. A component of the AMA’s strategic work starting in 2018 and beyond is to provide the physician perspective across health care technology sectors by promoting improved usability of and ready access to data for use in medical decision making and respect for the patient-physician relationship. Although extensive existing policies support the ideas and aims of RWD collection and the development of RWE, no policies specifically address the practice. This report sets the stage for additional information to come on the topic of RWD and RWE and provides foundational policy related to RWD and RWE to build on for other applications.

# REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2-I-19

Subject: Real-World Data and Real-World Evidence in Medical Product Decision Making

Presented by: Michael M. Miller, MD, Chair

Referred to: Reference Committee K

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## INTRODUCTION

Physicians are trained to implement the 5 steps of evidence-based practice (EBP) and rely on appropriate evidence to guide the clinical care they provide to their patients. The evidence relied upon in EBP has typically been generated from traditional randomized controlled trials (RCTs). Today, real-world data (RWD) and real-world evidence (RWE) are increasingly being used in health care decision making to augment evidence from RCTs.

The Council on Science and Public Health offers this overview of RWD and RWE to practicing physicians because it is important for all physicians to understand the genesis of data and derivation of evidence from sources other than traditional RCTs that is increasingly being used by the FDA in its approval of new products, new indications for products, or new labeling on products that are used in patient care. Although RWD and RWE have many applications in health care, this report remains narrow in scope and will focus only on the use of RWD and RWE that is fit for purpose to be used in medical product (that is, drug, biologic, and device) decision-making (Figure 1), such as the FDA's consideration of a new drug indication, labeling revision, or safety revision. The use of RWD and RWE as it applies to other topics, including augmented intelligence (AI), will be addressed at a later time.

RWD are the data relating to patient health status and/or the delivery of health care routinely collected from a variety of sources. RWE is the clinical evidence regarding the usage and potential benefits or risks of a medical product derived from analysis of RWD.<sup>1-3</sup> RWD and RWE are playing an increasing role in health care decisions. Additionally, the use of RWD and RWE to answer scientific questions and guide more effective and cost-efficient medical product decision making is an active area of engagement for regulatory agencies. Stakeholder groups are actively working on ways to improve the development and use of RWD and RWE across a range of clinical and regulatory activities.

The 21st Century Cures Act (Cures Act), signed into law in December 2016, is designed to accelerate medical product development and bring new innovations and advances faster and more efficiently to patients.<sup>4</sup> Among the provisions in the Cures Act is an added section to the Federal Food, Drug, and Cosmetic Act (FD&C Act) related to RWE which requires that the U.S. Food and Drug Administration (FDA) increase its use of evidence from clinical practice settings. Pursuant to this provision and the sixth Prescription Drug User Fee Act (PDUFA VI),<sup>5</sup> FDA created a framework for evaluating the potential use of RWE to support the approval of a new indication for a drug or biological product already approved or to support or satisfy drug post-approval study requirements.<sup>1</sup> The FDA under the fourth Medical Device User Fee Act (MDUFA IV)<sup>6</sup> is required

to, among other things, evaluate the published guidance in 2017, *Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices*.<sup>7</sup>

In addition to the FDA's activities related to RWD, the National Institutes of Health (NIH) has developed its first Strategic Plan for Data Science providing a roadmap for modernizing the NIH-funded biomedical data science ecosystem;<sup>8</sup> The National Academies of Sciences, Engineering, and Medicine (NASEM) remain engaged in RWD conversations with diverse stakeholders;<sup>9-12</sup> part of the Patient Centered Outcomes Research institute (PCORI) mandate is to improve the quality and relevance of evidence to advance health care;<sup>13</sup> and several thought leaders, including former FDA Commissioners, are commenting on the use of RWD for the advancement of health care.<sup>14-17</sup>

Many different types and sources of RWD exist, there is increasing availability of RWD, and new potential data sources are emerging. Both challenges and benefits to the use of these data exist. The Council on Science and Public Health initiated this report to inform physicians of the evolving use of RWD and RWE in medical product decision making. This report will define and clarify the current working definition and types/sources of RWD and RWE, evaluate challenges and benefits in using RWD, provide examples of RWD platforms and use of RWE, and explore considerations for generating RWE that is fit for regulatory purposes.

## METHODS

English-language articles were selected from a search of the PubMed database through August 2018 using the search terms "real-world data" and "real-world evidence." Due to the volume of results, the date range was limited to 2017 to present. Additional articles were identified from a review of the references cited in relevant, retrieved publications. Searches of websites of international and national government agencies and outcomes research organizations and associations were conducted to identify guidelines, position statements, and reports.

## OVERVIEW OF RWD AND RWE

RWD are collected from a variety of sources with varied quality, reliability, and applicability including electronic health records (EHRs) from hospitals, physician offices, and clinics (diagnoses and medical history); medical and billing claims; product and disease registries; administrative data; pharmacies (including dose, dose regimen, and route of administration of medications); laboratory, radiology, and diagnostic test results; cost studies; prospective observational data; vital records databases; primary and secondary care data; and patient-generated data, including from in-home-use settings, wearables, biosensors, remote monitoring devices, mobile devices and applications, consumer surveys, and social media (Figure 2).<sup>1,9,17</sup> Post-marketing data is the type of RWD currently used most often. RWD are typically more proximate to the patient and the patient experience; thus, they include primary source data, but they have a high potential for unstructured/inconsistent data collection and for missing data elements as compared to data collected for research or during clinical trials.<sup>18</sup>

The FDA is advancing a total product life cycle (TPLC) approach, a holistic approach that takes into account all of the steps and processes in the evolution of a medical product from conception to obsolescence, integrating information and knowledge across pre-market and post-market activities, to increase information-sharing and enhance decision-making. RWD and RWE are not a replacement for clinical trial data, but instead support the TPLC approach to medical product approval and surveillance; they will augment existing mechanisms which are known to have gaps, delays, and deficiencies that are inherent in any system that depends on active reporting by users.

1 RWE has the potential to inform therapeutic development, outcomes research, patient care, health  
2 care systems research, quality improvement, safety surveillance, and well-controlled effectiveness  
3 studies. RWE can provide answers to questions relevant to broad populations of patients that may  
4 not be possible or intended in the course of a traditional clinical trial and may reduce the number of  
5 individuals exposed to a faulty medical product and shorten the period of time before valid  
6 performance issues are identified and acted upon. Use of RWD and RWE may also save time and  
7 money throughout the TPLC. Additionally, RWE can be used to complement traditional clinical  
8 trials, generating more generalizable knowledge from larger, more inclusive populations of  
9 patients, providers, and health care delivery systems or settings that reflect actual use in practice.<sup>16</sup>

10  
11 However, it is important to note that the RWE generated from RWD has limitations and challenges  
12 including confidentiality and proprietary concerns, the cost and work required to convert data for  
13 use in analyses, and sharing and collaboration considerations.<sup>19</sup>

#### 14 15 *FDA RWE Program Framework*

16  
17 Former FDA Commissioner Scott Gottlieb, MD, recently noted that RWD and RWE are a top  
18 strategic priority for the FDA and the Agency is “committed to realizing the full potential of these  
19 tools in advancing the development of novel therapeutic products and strengthening our regulatory  
20 oversight of medical products across the life-cycle continuum.”<sup>20</sup> The recently published  
21 *Framework for FDA’s RWE Program* (framework), issued by the FDA’s Center for Drug  
22 Evaluation and Research (CDER) and Center for Biologics Evaluation and Research (CBER) is  
23 intended to develop a path for ensuring that RWE solutions are an integral part of the drug  
24 development and regulatory life cycle.<sup>20</sup>

25  
26 The CDER/CBER framework notes that the FDA’s work will be multifaceted and involve  
27 demonstration projects, stakeholder engagement, internal processes to promote shared learning and  
28 consistency in applying the framework, and the development of guidance documents to assist those  
29 using RWD to develop RWE to support FDA regulatory decisions.<sup>1</sup> The framework includes  
30 consideration of whether RWD are fit for use; whether the trial or study design used to generate  
31 RWE can provide adequate scientific evidence to answer or help answer the regulatory question;  
32 and whether the study conduct meets FDA regulatory requirements.<sup>1</sup>

33  
34 FDA currently uses RWE in safety surveillance and development of drugs for rare diseases, but  
35 there are other potential applications.<sup>18</sup> The FDA program will focus on exploring the potential of  
36 RWD/RWE to support regulatory decisions about product effectiveness. Specifically, FDA’s RWE  
37 Program will evaluate the potential use of RWE to support revisions to drug labeling such as  
38 changes in doses, dosing regimen or route of administration, and population or adding comparative  
39 effectiveness or safety information.<sup>1</sup> The framework also includes exploring the use of  
40 observational designs to generate RWE.

41  
42 The FDA’s Center on Devices and Radiological Health (CDRH) recently published guidance on  
43 the potential use of RWE for supporting initial decisions to approve or clear devices for use and  
44 includes the use a TPLC approach in their current strategic priorities.<sup>21</sup> The guidance also addresses  
45 the use of RWE for post-marketing assurance of medical device safety and performance.<sup>7</sup>  
46 Investigators have noted the high value of post-market evidence in evaluating the performance of  
47 modern medical devices outside of the context of a controlled clinical trial and have also noted that  
48 RWE can supplement or replace currently required post-approval studies, saving money and time.<sup>22</sup>

49  
50 CDER and CBER routinely use RWE to support post-marketing safety evaluation and, to a limited  
51 extent, to evaluate the effectiveness of medical products in certain rare diseases. CDER’s and

1 CBER's experience with Sentinel, a program described in more detail in Appendix A, is informing  
2 policy, guidance, frameworks, methods and platforms going forward. Sentinel is leading the way  
3 for CDRH to use RWE, from the National Evaluation System for Health Technology (NEST), in its  
4 product evaluations in pre- and post-market decisions; NEST is another program described in  
5 Appendix A.

#### 6 7 *Fit for Regulatory Purpose*

8  
9 The FDA states that any RWD/RWE used for regulatory purposes, including drug development  
10 and regulatory review, must be fit for purpose – it must be high-quality data that can support  
11 regulatory decision making and improve public health. Fit for purpose RWD requires data  
12 relevancy and data quality. The process of producing a fit for purpose RWD set begins with  
13 selection of one or more data sources, then cleaning, transforming, and linking data. Obtaining  
14 curated, high quality, unbiased data is a rate limiting step to obtaining RWE, which is labor  
15 intensive and costly.<sup>3</sup>

16  
17 The Duke-Margolis Center for Health Policy and FDA published a framework in which they  
18 propose that developing RWE fit for regulatory purposes should be guided by the interplay of the  
19 regulatory question a sponsor seeks to address, the clinical context within which RWE is being  
20 generated, the availability of RWD that is both relevant and of acceptable quality; and the  
21 application of trusted methods for turning RWD into actionable evidence.<sup>23</sup>

22  
23 When RWE is identified and intended to be used in regulatory contexts, for example in the FDA's  
24 consideration of a new drug indication, labeling revision, safety revision, or risk-benefit profile,  
25 there are unique challenges that require careful consideration to characterize it as robust and  
26 representative of the population of interest.<sup>3</sup> Not all research questions may be suitable for  
27 answering with RWE, traditional inferential statistics may be unable to identify clear treatment  
28 effects given variations in treatment effect definitions, clinical practice, and partial adherence to  
29 treatment, and it remains unclear how regulatory standards and compliance requirements designed  
30 for traditional clinical trials apply to RWE.<sup>23</sup> Additional work needs to be done to clarify the types  
31 of RWD and RWE that are robust enough to provide information to support regulatory guidance  
32 and decisions.<sup>24</sup>

#### 33 34 *RWE vs. Traditional Clinical Trials*

35  
36 RCTs have traditionally served as the gold standard for generating evidence about medical  
37 products. RCTs are optimized to control variability and maximize data quality to produce data  
38 essential for regulatory approval by answering regulators' questions related to efficacy and  
39 safety.<sup>16,25</sup> RCTs are often conducted with a narrowly defined group of patients and many  
40 investigators express concern that RCTs may not reflect the broad patient populations that will be  
41 exposed to an approved treatment in the real-world,<sup>23</sup> and that specific therapeutic interventions  
42 may perform differently in different patient cohorts based on age, gender, race, ethnicity, disease  
43 severity, comorbidities, or polypharmacy.<sup>17,25</sup> RCTs are also complex, expensive, time consuming,  
44 and cannot answer all questions about a product or intervention.<sup>10</sup> Some estimates state that clinical  
45 trials can take as long as seven years and cost more than \$2 billion.<sup>17</sup> The FDA also recognizes that  
46 overly complex RCTs and unnecessary data collection can deter patient enrollment and discourage  
47 the development of second and third-to-market innovations and reducing competition and lowering  
48 prices.

49  
50 According to the FDA framework, evidence from traditional clinical trials will not be considered  
51 RWE, but various hybrid or pragmatic trial designs and observational studies could generate

RWE.<sup>1,14</sup> Traditional RCTs, often referred to as explanatory trials generally measure efficacy – the benefit of a treatment under ideal conditions. Pragmatic trials measure effectiveness – the benefit of treatment in clinical practice. Pragmatic trials can test the same intervention as a traditional RCT, but they are conducted in real-world clinical practice settings, with typical patients and by qualified clinicians who may not have a research background, as detailed in the Salford Lung Study below.<sup>26</sup> Augmenting traditional RCTs with data from a broader, more diverse group of patients in different practice settings can increase the generalizability of trials, answer questions about subpopulations for treatments, or demonstrate proof of value to payers and patients, as has been done in some trials conducted within clinical registry populations.<sup>2,11,17</sup> Many opportunities exist for leveraging RWE during the life cycle of product development (Figure 3).

Benefits of using RWD/RWE to support RCTs includes more efficient and targeted recruitment of patients for RCTs; expediting hypotheses generation to inform RCT design; identification of subpopulations with higher risk-benefit ratios; supporting the identification of drug development tools, such as biomarkers; trial feasibility assessment; supporting geographically distributed research cohorts; and improving the efficiency of studies for drugs approved under the FDA's expedited programs.<sup>1,17</sup>

#### PRIVACY, SECURITY, AND ACCESSABILITY

While many opportunities to leverage RWD and RWE to support regulatory efforts related to medical products exist, there are also barriers to their use.<sup>17</sup> Among the biggest barriers to the use of RWD and RWE are data accessibility, privacy, and security concerns. While increasing the use of patient data is a priority for FDA and national thought leaders, also increasing is public, and AMA, concern about the secondary use of personal information. Noteworthy is a study evaluating RCT participant concerns about the risks of data sharing which found that most participants most were willing to share their data for a wide range of uses provided that adequate security safeguards were in place.<sup>27</sup>

The Health Insurance Portability and Accountability Act of 1996 (HIPAA), safeguards the collection, storage, and disclosure of protected health information for covered entities, which includes health care entities and practitioners that electronically transmit health information, health plans, and clearinghouses.<sup>28</sup> HIPAA rules do not apply to deidentified health data, even as methods to reidentify individuals from other sources proliferate.<sup>29</sup> Privacy conversations related to RWD and RWE focus on ways to decrease risk of reidentifying deidentified data, data minimization, identifiers to remove from data sets, and expanding penalties and civil remedies available for data breaches and misuse, including reidentification attempts.<sup>30</sup>

Access to RWD requires aggregation of the health data, which are usually stored in multiple silos and can suffer from incompatibility and data quality issues. Increasing the use of these data is challenging for several reasons including confidentiality and proprietary issues, costs and labor associated with raw data transformation, and incentives for data holders to share information that outweigh the disadvantages (for example, unauthorized use and competition).<sup>19</sup>

Data enclaves, secure networks through which confidential data can be stored and disseminated, are becoming popular.<sup>19,31</sup> Data enclaves address two major barriers related to data sharing: data owners can maintain operational control of their data (granting permissions for analysis requests) and they eliminate the need to construct new, secure systems for each query or study.<sup>19</sup> Multiple enclaves from different data owners can be linked to create data networks in which the systems format their data identically and execute identical analytic programs on the data. Typically, data

enclaves in a network share aggregate results. Some data enclave networks, such as the FDA's Sentinel System, include the records of more than 100 million individuals.<sup>19</sup>

Networks can be centralized (for example, registries), decentralized (for example PCORnet and NEST), or distributed (for example, Sentinel). In a centralized system, all users are connected to a central network owner that stores data for others to access. Decentralized systems do not have one central owner, and instead use multiple central owners, each of which usually stores a copy of the resources users can access. In these models, data owners retain patient-level data behind the firewall of their institution, and issues related to the use and reuse of data resolved by the participants in the network.<sup>32</sup> Distributed systems are similar to decentralized and do not have a single, central owner; users have equal access to data and share ownership of the data.

Additionally, patients are taking more control of their own data and creating shareable health records by authorizing data sharing from mobile applications, physician visits, pharmacy records, and more. Patients can share their aggregated data upon request using an application such as Apple's new Health app. Using the Health app, patients and providers can share data and interact on Apple devices.<sup>33</sup> Over 350 health care institutions currently support this type of shareable health information.<sup>34</sup> However, substantial concerns remain about the potential for data misuse by third parties, especially when HIPAA does not apply.

## DATA NETWORKS

Many stakeholders, including federal agencies, health systems, payers, and clinicians have made significant progress through investments in the curation, linkage, and analysis of electronic health-related data generated during the course of patient care. Much of these data are housed in clinical data warehouses or enclaves, organized into common data models, refreshed periodically, and subjected to quality assurance checks. Many of the networks are based on voluntary, nonexclusive collaborations in which institutions elect to participate in multi-center studies.

Several independent networks established and active for post-market medical product surveillance are now being leveraged to contribute to public-private collaboration for improved population-based evidence generation related to medical products on a much larger scale. Please see Appendix A for more details about several data networks.

## RWE USE CASES

Although currently the most common use of RWE is retrospective analysis of existing data, increasingly, clinical trials are being conducted in real-world settings to improve the generalizability of results and to reduce inefficiencies related to establishing separate research infrastructures. These pragmatic clinical trials are conducted using existing clinical infrastructure to prospectively test interventions in every-day situations. Please see Appendix B for examples of RWE use cases.

## CURRENT AMA POLICY

While no AMA policy currently addresses RWD or RWE specifically, AMA has extensive policy on related topics that were developed prior to the propagation of RWD and RWE. The relevant topics include data, registries, post-market surveillance, effectiveness evaluation, and clinical trials/drug approval. Because of the volume of related AMA policies referenced, please see Appendix C for the full text of policies.

Globally, AMA Policy H-100.992, “FDA,” supports the principles that an FDA decision to approve a new drug, to withdraw the approval of a drug, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or post-market incident reports.

#### *Data-related Policy*

AMA Task Force to Address the Release of Physician Information. In 2007, AMA convened a task force to address the release of physician information. This task force was formed in response to physician profiling programs and “efficiency ratings.” The task force assisted the AMA in the creation of Principles for the Public Release and Accurate Use of Physician Data, which provides a framework for the AMA to address the appropriate release and use of physical data in evaluating physician performance (“physician-specific data”). The task force also thought it was important for the AMA to specifically craft policy regarding the release and use of physician data by the federal government for all purposes (“physician data”). Board of Trustees (BOT) Report 18-A-09 details this task force and resulting recommendations that address safeguards for the release of physician data and physician profiles. The resulting AMA policy is guided by seven main principles: patient privacy safeguards; data accuracy and security safeguards; transparency requirements; review and appeal requirements; physician profiling requirements; quality measurement requirements; and patient satisfaction measurement requirements (Policies H-406.990, “Work of the Task Force on the Release of Physician Data,” H-406.989, “Work of the Task Force on the Release of Physician Data,” H-406.991, “Work of the Task Force on the Release of Physician Data,” and H-406.996, “Use and Release of Physician-Specific Health Care Data”).<sup>57</sup>

Council on Legislation Workgroup on Health Care Data Transparency. In 2014, AMA’s Council on Legislation (COL) established a workgroup to focus on health care data transparency. The intent of the workgroup was to develop guiding principles on the data and transparency efforts that should be pursued in order to improve care quality, reduce costs, prioritize the right set of regulatory reforms, and highlight innovative uses of health care data that benefit physicians. BOT Report 6-A-15 provides background on the health care data transparency and details the work of the COL.<sup>58</sup>

The workgroup noted that our AMA has extensive policy on physician data transparency; however, it was created at a time when most of this information was not widely available and accordingly, focused on safeguards against releasing this information. The workgroup recognized the work of the 2007 task force, built on their policy recommendations (seven outlined principles) to reflect the new opportunities and potential uses of this information, and identified three components of a data transparency framework: transparency objectives and goals; data transparency resources; and challenges to transparency (Policy H-406.987, “Medical Information and Its Uses”).

The framework principles are intended to guide and develop AMA advocacy and policy as more data are sought by stakeholders and new uses of this information emerge. The framework principles recognize the new data environment and the need for physicians to engage in this area. Noteworthy statements in this policy include facilitation of more proactive use of health care data; support of the removal of barriers to accessing additional information from other payers and care settings, focusing on data that is valid, reliable, and complete; supporting definitions of quality based on evidence-based guidelines; promotion of efforts by clinical data registries, regional collaborations, Qualified Entities, and specialty societies to develop reliable and valid performance measures, increase data utility, and reduce barriers that currently limit access to and use of the health care data; and support of improvements in EHRs and other technology to capture and access data in uniform formats.



Data Ownership. Informational BOT Report 21-A-18 provided an overview of the current laws and regulations at the state and federal levels that address ownership, access, and use of patient data.<sup>59</sup> The report notes the importance of patients having appropriate access to their data and physicians having the tools and controls they need to be good stewards of their patients' information while at the same time having the ability to share information to seamlessly coordinate the best care. Additionally, Policy D-315.984, "Ownership of Claims Data," notes that our AMA will continue to monitor federal and state activities impacting the exchange of physician-generated health information, including claims data.

Additional Data-related Policy. Policy H-406.999, "Goal of Health Care Data Collection," notes the AMA's support for collection of health care data that can be used for education of both consumers and providers and made available to physicians and medical societies. AMA policy supports compliance with HIPAA Privacy and Security Rules and data accessibility to authorized users for purposes of treatment, public health, patient safety, quality improvement, medical liability defense, and research (Policy H-315.973, "Guiding Principles for the Collection, Use and Warehousing of Electronic Medical Records and Claims Data").

#### *Data Registries Policy*

AMA policy encourages multi-stakeholder efforts to develop and fund clinical data registries for the purpose of facilitating quality improvements and research that result in better health care, improved population health, and lower costs. Additionally, policy encourages physicians and physician groups to participate in efforts to advance the development and use of clinical data registries and provides guidelines to help maximize opportunities for clinical data registries to enhance the quality of care provided to patients. AMA policy also notes that clinical registry data may be used to meet third-party quality reporting requirements with suggested guidelines and encourages a national clinical trial registry to promote subject safety, research quality, and to document previous trial participation (Policies H-450.933, "Clinical Data Registries" and D-460.972, "Creation of a National Registry for Healthy Subjects in Phase I Clinical Trials").

#### *Post-Market Surveillance/Adverse Event Reporting Policy*

Several policies note our AMA's support of post-market surveillance and adverse event reporting, including Ethical Opinion 8.8, "Required Reporting of Adverse Events," which notes physicians' responsibility to report suspected adverse events resulting from the use of a drug or medical device and Policy H-120.958, "Supporting Safe Medical Products as a Priority Public Health Initiative," which encourages proper reporting of adverse events. Additional policies comment on the utility of manufacturer-conducted post-market surveillance to document long-term safety, effectiveness, and acceptance, encourages manufacturers to better study medication effects in pre- and post-marketing clinical trials, encourages mechanisms for data collection, monitoring, and analysis of medication-related problems by age group, and encourages the sharing of post-market surveillance information with the FDA (Policies H-75.990, "Development and Approval of New Contraceptives," and H-100.968, "Improving the Quality of Geriatric Pharmacotherapy").

Policy D-100.982, "Enhanced Physician Access to Food and Drug Administration Data," urges the FDA to apply new tools to gather data after drugs are approved for marketing, including a broader use of targeted post-approval studies, institution of active and sentinel event surveillance, and data mining of available drug utilization databases.

## *Effectiveness Evaluation Policy*

Policy H-110.986, “Incorporating Value into Pharmaceutical Pricing,” supports value-based pricing of pharmaceuticals that is evidence-based and the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes.

## *Clinical Trials/Drug Approval Policy*

AMA has long-standing policy supporting clinical trials. Our AMA supports the development of transparent, collaboratively constructed clinical pathways that are implemented in ways that promote administrative efficiencies for both providers and payers; promote access to evidence-based care for patients; recognize medical variability among patients and individual patient autonomy; promote access to clinical trials; and are continuously updated to reflect the rapid development of new scientific knowledge (Policy H-410.948, “Clinical Pathways”). Additional policies include urging access to original source safety data from industry-sponsored trials upon request; support for ample federal funding of medical research, including basic biomedical research, translational research, clinical research and clinical trials, health services research, outcomes research, and prevention research; and support for accounting for the possible role of sex as a biological variable in vertebrate animal and human studies (Policies D-460.970, “Access to Clinical Trial Data,” H-460.926, “Funding of Biomedical, Translational, and Clinical Research,” and H-525.991, “Inclusion of Women in Clinical Trials”).

## SUMMARY

Data are more widely collected, available, and accessible than in the past. Evidence and opportunities are mounting on ways to leverage new data sources as RWD and RWE to support regulatory efforts and value-based payment arrangements for medical products, yet privacy accessibility and privacy concerns remain. The FDA is actively engaged in understanding the potential of RWE to meet the established standards for adequate and well-controlled clinical investigations and pursuing its integration into drug development and regulatory review, the support of new indications for an approved drug, and its ability to satisfy post-approval study requirements. Advocates note that the use of RWD and RWE is crucial for incorporating patient experiences, currently often a gap in knowledge, into decision-making by drug companies, insurers, providers, and regulators.

In a 2017 Real-World Evidence Benchmark Survey, Deloitte noted that many health care stakeholders, including life sciences companies and others (payers, providers, regulators, and patients) are increasingly making high-impact decisions and attempting to demonstrate value using RWD.<sup>60</sup> The results of this survey illustrate that with its increasing availability and recognized worth, RWE has the potential to support, improve, and potentially accelerate the delivery of safe and cost-effective medical products.

If RWD and RWE are to be effectively leveraged for public health purposes, then shared learning and collaboration across clinicians, patients, health care systems, pharmaceutical companies, and regulators are necessary. An understanding of the limitations and barriers associated with the use of RWD must also be acknowledged and addressed. Recently, a group of former FDA commissioners offered recommendations and suggested requirements for advancing the generation and use of RWE to evaluate effectiveness and safety of drugs, biologics, and devices including adequate funding, regulatory clarity, access to data, improved data reliability and relevance, assured privacy

and confidentiality, innovative, new models of drug development, and cooperation and collaboration.<sup>17</sup>

A component of the AMA's strategic work starting in 2018 and beyond is to provide the physician perspective across health care technology sectors by promoting improved usability of and ready access to data for use in medical decision making and respect for the patient-physician relationship. Although extensive existing policies support the ideas and aims of RWD collection and the development of RWE, no policies specifically address the practice. As a leader in American medicine, our AMA has a unique opportunity to be a part of the evolving conversation related to the use of RWD and RWE for regulatory purposes.

## RECOMMENDATIONS

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

1. Our AMA supports the generation and use of real-world data (RWD) and real-world evidence (RWE) fit for regulatory purpose to: (a) evaluate effectiveness and safety of medical products, while assuring patient privacy and confidentiality; (b) improve regulatory decision-making; (c) decrease medical product costs; (d) increase research efficiency; (e) advance innovative and new models of drug development; and (f) improve clinical care and patient outcomes. (New HOD Policy)
2. Our AMA supports the aim of the U.S. Food and Drug Administration (FDA) to expand and clarify the use RWD and RWE in regulatory decision-making including in:
  - a. understanding the potential of RWE to meet the established standards for adequate and well-controlled clinical investigations;
  - b. pursuing the integration of RWE into medical product development and regulatory review; and
  - c. utilizing RWE to support new indications for approved medical products, and its ability to satisfy post-approval study requirements. (New HOD Policy)
3. Our AMA supports that there be adequate funding of data infrastructure to allow for transparent data management capabilities, improved access to data by clinicians, especially physicians, as well as researchers and other stakeholders, and improved reliability and relevance of data. (New HOD Policy)
4. Our AMA supports cooperation and collaboration of stakeholders to facilitate the collection and use of RWD and RWE that is deemed fit for regulatory purpose. (New HOD Policy)
5. Our AMA will evaluate and develop a response to the educational needs of physicians seeking to understand the use of fit for purpose RWD and RWE in clinical practice. (New HOD Policy)
6. That Policy H-100.992, "FDA," be amended by addition to read as follows:
 

H-100.992, "FDA"

  - (1) Our AMA reaffirms its support for the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials, real-world data (RWD) fit for regulatory purpose, and/or postmarket incident reports as provided by statute; (b) this evidence should be evaluated by the FDA, in consultation with

- 1 its Advisory Committees and expert extramural advisory bodies; and (c) any risk/benefit  
2 analysis or relative safety or efficacy judgments should not be grounds for limiting access  
3 to or indications for use of a drug unless the weight of the evidence from clinical trials,  
4 RWD fit for regulatory purpose, and postmarket reports shows that the drug is unsafe  
5 and/or ineffective for its labeled indications.
- 6 (2) The AMA believes that social and economic concerns and disputes per se should not be  
7 permitted to play a significant part in the FDA's decision-making process in the course of  
8 FDA devising either general or product specific drug regulation.
- 9 (3) It is the position of our AMA that the Food and Drug Administration should not permit  
10 political considerations or conflicts of interest to overrule scientific evidence in making  
11 policy decisions; and our AMA urges the current administration and all future  
12 administrations to consider our best and brightest scientists for positions on advisory  
13 committees and councils regardless of their political affiliation and voting history. (Modify  
14 Current HOD Policy)
- 15
- 16 7. That Policy D-100.982, "Enhanced Physician Access to Food and Drug Administration Data,"  
17 urging the FDA to apply new tools to gather data after drugs are approved for marketing,  
18 including a broader use of targeted post-approval studies, institution of active and sentinel  
19 event surveillance, and data mining of available drug utilization databases, be reaffirmed.  
20 (Reaffirm Current HOD Policy)
- 21
- 22 8. That Policy H-110.986, "Incorporating Value into Pharmaceutical Pricing" supporting value-  
23 based pricing of pharmaceuticals that is evidence-based and the result of valid and reliable  
24 inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical  
25 data registries, comparative effectiveness research, and robust outcome measures that capture  
26 short- and long-term clinical outcomes, be reaffirmed. (Reaffirm Current HOD Policy)
- 27
- 28 9. That Policy H-406.987, "Medical Information and Its Uses," identifying three components of a  
29 data transparency framework, be reaffirmed. (Reaffirm Current HOD Policy)
- 30
- 31 10. That Policy H-410.948, "Clinical Pathways," supporting the development of transparent,  
32 collaboratively constructed clinical pathways that are implemented in ways that promote  
33 administrative efficiencies for both providers and payers; promote access to evidence-based  
34 care for patients; recognize medical variability among patients and individual patient  
35 autonomy; promote access to clinical trials; and are continuously updated to reflect the rapid  
36 development of new scientific knowledge, be reaffirmed. (Reaffirm Current HOD Policy)
- 37
- 38 11. That Policy H-450.933, "Clinical Data Registries," encouraging multi-stakeholder efforts to  
39 develop and fund clinical data registries to facilitate quality improvements and research that  
40 results in better health care, improved population health, and lower costs be reaffirmed.  
41 (Reaffirm Current HOD Policy)
- 42
- 43 12. That Policy D-460.970, "Access to Clinical Trial Data," urging the FDA to investigate and  
44 develop means by which scientific investigators can access original source safety data from  
45 industry-sponsored trials upon request; be reaffirmed. (Reaffirm Current HOD Policy)

Fiscal Note: \$50,000

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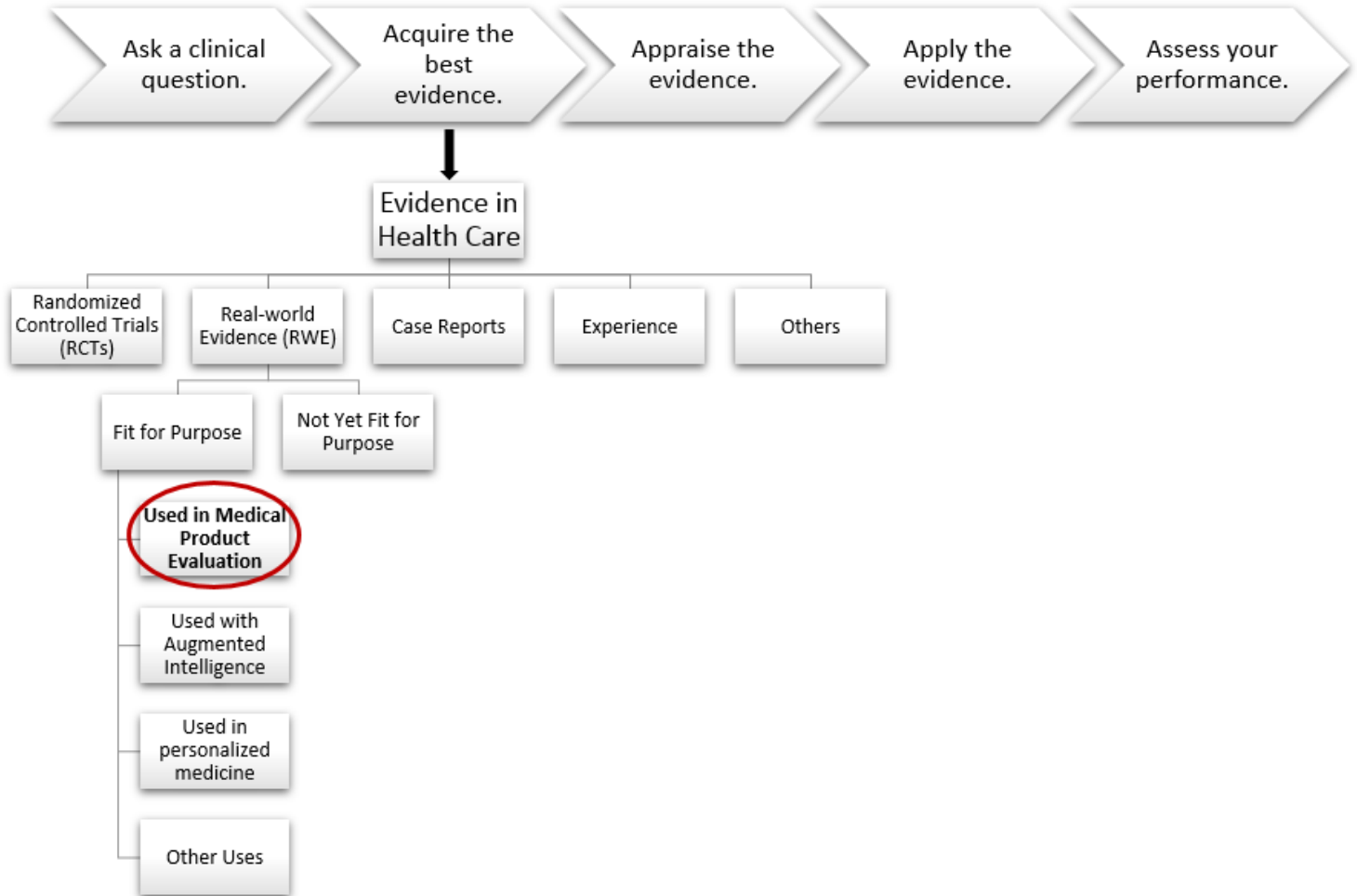
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**Figure 1.**

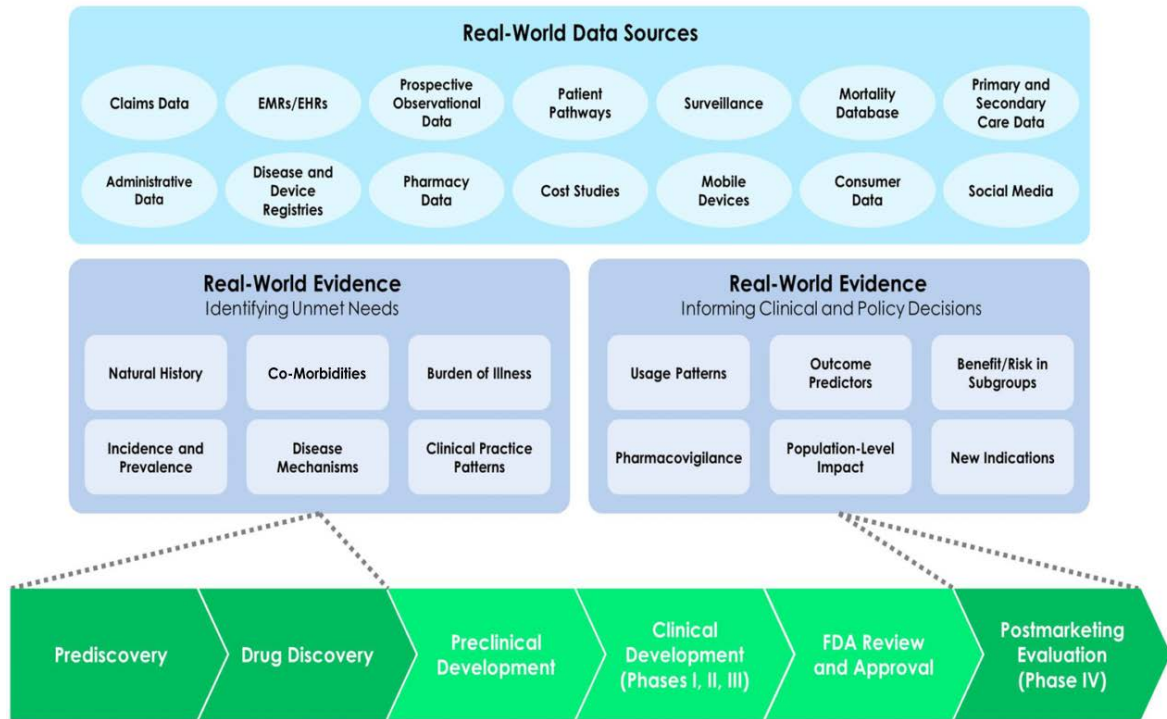
**Scope of This Report: Where does RWE fit in to Evidence-based Practice?**

5 Steps of Evidence-based practice:



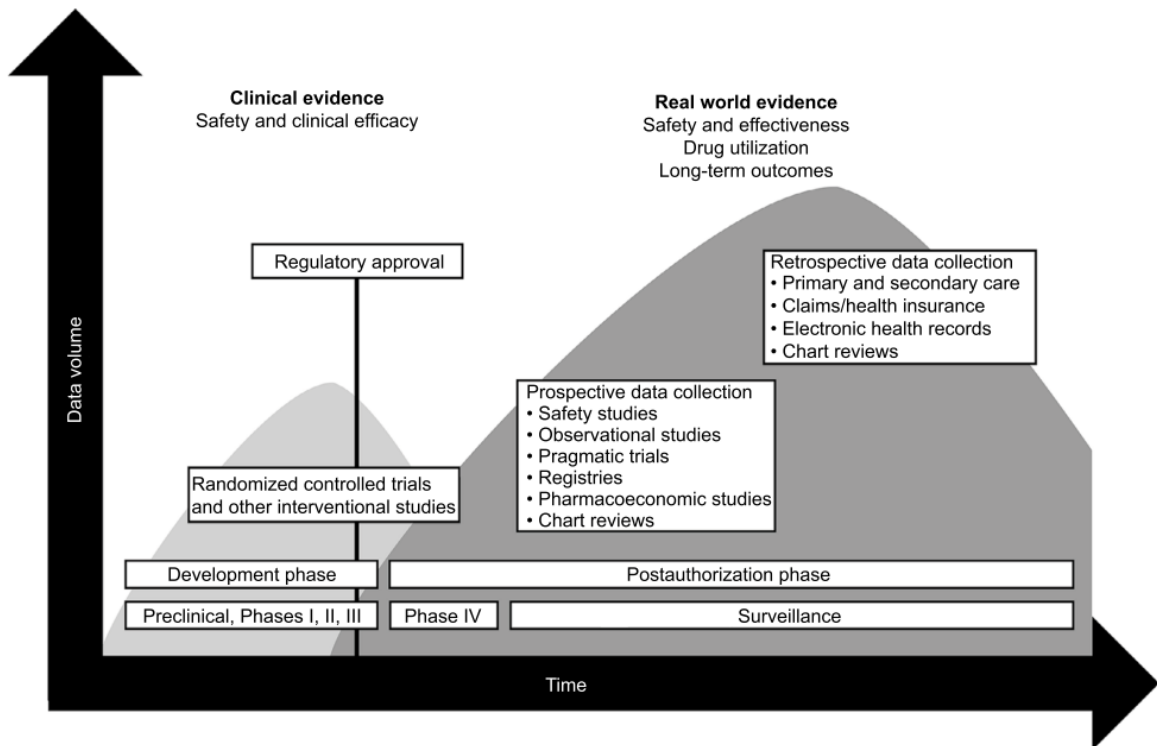


**Figure 2.**



From <sup>9,25</sup>

**Figure 3.**



From <sup>24</sup>

## APPENDIX A

## Data Networks

This is a non-comprehensive list of example data networks housing and providing RWD per request. Please see Box 1 for links to more information on the networks.

*The Sentinel Initiative*

The Sentinel Initiative, launched in 2008, began as a Congressional mandate for the FDA to establish a public-private partnership to develop a medical product safety surveillance system using existing data.<sup>35</sup> The FDA partnered with over 200 health systems leaders, pharmacoepidemiologists, clinicians, data scientists, patient representatives, and more from 31 health plans and academic organizations to form the network.<sup>15</sup>

The principal component of the Sentinel Initiative is the Sentinel System, a multi-site, privacy-preserving, curated distributed data infrastructure, and suite of analysis tools.<sup>36,37</sup> The FDA has used Sentinel to conduct more than 250 analyses, and it is now embedded in the regulatory review process through the Active Risk Identification and Analysis (ARIA) process.<sup>38</sup> ARIA is comprised of pre-defined, parameterized, reusable routine querying tools, and undergoes continuous quality checks and refreshes so analyses can be done quickly and efficiently for medical product safety surveillance.

The FDA recognizes the interest in generating effectiveness evidence and is exploring the potential of the Sentinel System to support studies of efficacy. As a part of this effort, the FDA is funding a study to explore whether observational methods can be used to replicate the results of approximately 30 clinical trials designed to provide evidence about the effectiveness of a drug. This project will assist the FDA in understanding how observational methods can be applied to evaluating drug effectiveness and may have the potential to provide evidence to inform regulatory decision-making.<sup>2</sup>

Additionally, FDA is increasing the scope of safety signals the Sentinel System evaluates by identifying opportunities to improve data, tools, and methods and has completed or has underway several projects related to patient and product safety:

- Sentinel data have informed regulatory decisions made by the FDA's Center for Drug Evaluation and Research and, in the past 2 years, have eliminated the need for post-marketing studies on nine potential safety issues associated with five products, as an example, ustekinumab and serious infections.<sup>15</sup>
- To explore how randomized trials can be conducted in real-world settings, the FDA is supporting the first randomized clinical trial in Sentinel. The IMPACT-Afib trial is testing an educational intervention to address underuse of effective medications to reduce the risk of stroke in patients with atrial fibrillation.<sup>2,15,39</sup>

FDA released a Sentinel System Five-Year Strategy which details goals for the multi-purpose national data and scientific resource center for evidence-generation that can inform health care decision-making.<sup>40</sup> The strategy also details several data improvements FDA plans to prioritize including the following:

- Scaling capabilities related to the mother-infant linkage to evaluate in-utero exposure, medical product usage during pregnancy, and post-natal outcomes.
- Working to integrate national and state registry linkages including the National Death Index (NDI), Surveillance Epidemiology and End Results (SEER), and other rare-disease registries.
- Continuing to increase the number of validated Health Outcomes of Interest (HOIs) through medical record review, drawing from increased availability of EHR linkages.
- Expanding linkages to EHR data sources from Sentinel System Data Partners and exploring potential expansion to incorporate other data partners, such as the National Patient-Centered Clinical Research Network (PCORnet).
- Increasing the availability of full medical records, including improved access to the Medicare chart review process, prioritizing electronic sources from integrated delivery systems.

### *PCORnet*

PCORnet originated with, and evolved through funding support from the Patient-Centered Outcomes Research Institute (PCORI) to develop a range of useful resources and partnerships. Currently, PCORnet is a network that supports patient-centered research and answers questions important to patients, caregivers, clinicians, and the broader health care community.<sup>41</sup>

PCORnet is a decentralized network that is governed by a steering committee composed of patient representatives and leaders from PCORnet's constituent organizations.<sup>42</sup> PCORnet supported the largest study of bariatric surgery devices in adolescents.<sup>43</sup>

### *MDEpiNet*

The Medical Device Epidemiology Network (MDEpiNet) is a global public-private partnership that seeks to advance the collection and use of RWD to improve patient outcomes.<sup>44</sup> MDEpiNet brings together stakeholders from across the health ecosystem to develop and improve RWD infrastructure and carry out studies to better understand how devices perform in the real-world. MDEpiNet is also focused on developing better methods and medical device registries for medical device surveillance and post-market data collection.

### *NEST*

In 2016, the FDA awarded the Medical Device Innovation Consortium (MDIC) \$3 million to establish the National Evaluation System for health Technology Coordinating Center (NESTcc). The MDIC was in 2012 as the first public-private partnership created with the objective of advancing medical device regulatory science throughout the total product life cycle.<sup>45</sup> NESTcc aims to support sustainable generation and use of timely, reliable, and cost-effective RWE throughout the lifecycle of medical devices using RWD to support decision-making for: regulatory purposes, patients and clinicians in clinical situations, health systems purchasing, and payer coverage.<sup>46,47</sup> NESTcc has established partnerships with twelve network collaborators, including MDEpiNet, that represent more than 195 hospitals and 3,942 outpatient clinics to use high-quality RWD from various sources.

The goals of NESTcc include moving from passive surveillance to active, real-time surveillance, leveraging RWE to support regulatory decisions related to medical devices, making better use of data generated in the course of clinical care or by patients themselves, and moving away from lengthy, one-off, cost-prohibitive studies to an ecosystem that supports more routine evidence generation. NEST is setting data quality and methods standards related to observational and randomized studies; designating demonstration projects to assess feasibility and the ability to capture the data needed to support a range of studies and analyses; and offering value through products and services to key stakeholders in the ecosystem.

### *Registries*

Device-specific and condition-specific registries have played an important role in generating clinical evidence on safety and effectiveness by collecting, curating, and analyzing data related to medical product use in routine practice over time.<sup>32</sup> Registries collect patient-level data from health systems or physician practices through various pathways and are used for many purposes, including short- and long-term surveillance, fulfillment of post-market observational study commitments for regulatory bodies, and comparative safety and effectiveness assessments, including those in under-studied subpopulations.<sup>48,49</sup> By linking medical product exposures and long-term outcomes, registries permit follow-up that can span decades.<sup>48</sup>

### *Others*

The TREND Community data collection platform and PatientsLikeMe are examples of online platforms created that allow for the systematic gathering of patient experience data.<sup>50,51</sup> These online networks of consented patients and caregivers living with diseases are engaged in community discussions and sharing patient experiences. The communities connect scientists, doctors, therapists, research organizations, patients,

and caregivers in real time and enable them to directly organize experiments and crowd-source the collection of RWD.

Over the past several years, several companies have emerged that specialize in the collection, curation, analysis of health care technology data. For example, Aetion®, a software platform company delivering the real-world analytics and RWE, recently partnered with the FDA and Brigham and Women's Hospital/Harvard Medical School to use its software platform to re-create RCTs through RWE. The study aims to demonstrate the value of RWE as an accelerant to drug approval, particularly for supplemental indications.<sup>52</sup>

**Box 1. More information on RWD networks.**

1. [Report an adverse event](#): Any adverse event experience by patients should be reported to the [FDA Adverse Event Reporting System \(FAERS\)](#)
2. [Sentinel](#)
3. [PCORnet](#)
4. [MDEpiNet](#)
5. [NEST](#)

## APPENDIX B

## RWE Use Cases

*Salford Lung Study (Pragmatic (hybrid) Clinical Trial)*

The Salford Lung Study assessed the effectiveness and safety of fluticasone furoate in patients with chronic obstructive pulmonary disease (COPD). In this 12 month, open-label, phase 3, multicenter study, 2799 patients with COPD were randomized to a once-daily inhaled combination of fluticasone furoate and vilanterol, or to continuation of their existing therapy. This study analyzed EHR data collected during all interactions of consenting patients with physicians, pharmacists and hospitals.<sup>53</sup>

*ADAPTABLE (Pragmatic (hybrid) Clinical Trial)*

The ADAPTABLE (Aspirin Dosing: A Patient-Centric Trial Assessing Benefits and Long-Term Effectiveness) trial compares two commonly used doses of aspirin by randomizing 20,000 patients. The trial is integrated into routine clinical care with minimal inclusion/exclusion criteria and no treatment protocol requirement beyond the assignment to one of the two doses of aspirin. ADAPTABLE is using EHRs and claims data (through PCORnet) to capture primary endpoints such as death, hospitalization for non-fatal myocardial infarction or non-fatal stroke, and secondary endpoints such as coronary revascularization procedures, hospitalization for serious bleeding, and other patient-reported outcomes.<sup>1,54</sup>

*VALIDATE-SWEDEHEART (Pragmatic (hybrid) Clinical Trial)*

The VALIDATE-SWEDEHEART (The Bivalirudin versus Heparin in ST-Segment and Non-ST-Segment Elevation Myocardial Infarction in Patients on Modern Antiplatelet Therapy in the Swedish Web System for Enhancement and Development of Evidence-Based Care in Heart Disease Evaluated According to Recommended Therapies Registry) Trial was a registry-based, multicenter trial in which patients were randomized to bivalirudin or heparin during percutaneous coronary intervention. The endpoint was myocardial infarction, all-cause mortality, and major bleeding at 6 months. A national population-based Swedish registry platform was used for continuous enrollment, randomization, data collection, and follow up.<sup>1,55</sup>

*PatientsLikeMe – ALS (Patient Generated RWD)*

A PatientsLikeMe community of patients with amyotrophic lateral sclerosis (ALS), a progressive and fatal neurodegenerative condition with no effective treatments, crowdsourced an observational study. Many patients with ALS in the community reported using lithium carbonate, which had shown promise in a small study but did not have regulatory approval for use in ALS. An observational study of drug usage and disease progression from quantitative data recorded by members of the community and matched control patients was conducted. No difference in disease progression was observed after 12 months between the two study groups; similar results were reported in a subsequent RCT. Experts note that these types of observational studies are not a substitute for RCTs, but suggest that data reported by patients in online health communities could be useful for accelerating clinical discoveries and evaluating the effectiveness of drugs in use.<sup>56</sup>

## APPENDIX C

### Related AMA Policy

#### **H-75.990, “Development and Approval of New Contraceptives”**

Our AMA (1) supports congressional efforts to increase public funding of contraception and fertility research; (2) urges the FDA to consider the special health care needs of Americans who are not adequately served by existing contraceptive products when considering the safety, effectiveness, risk and benefits of new contraception drugs and devices; and (3) encourages contraceptive manufacturers to conduct post-marketing surveillance studies of contraceptive products to document the latter's long-term safety, effectiveness and acceptance, and to share that information with the FDA. (BOT Rep. O, I-91 Reaffirmed: Sunset Report, I-01 Modified: CSAPH Rep. 1, A-11)

#### **H-100.968, “Improving the Quality of Geriatric Pharmacotherapy”**

Our AMA believes that the Food and Drug Administration should encourage manufacturers to develop low dose formulations of medications commonly used by older patients in order to meet the special needs of this group; require geriatric-relevant labeling for over-the-counter medications; provide incentives to pharmaceutical manufacturers to better study medication effects in the frail elderly and oldest-old in pre- and post-marketing clinical trials; and establish mechanisms for data collection, monitoring, and analysis of medication-related problems by age group. (CSA Rep. 5, A-02 Reaffirmation A-10)

#### **D-100.982, “Enhanced Physician Access to Food and Drug Administration Data”**

Our AMA will: (1) urge the FDA to collaborate with physician organizations to develop better risk communication vehicles and approaches; (2) urge the FDA to apply new tools to gather data after drugs are approved for marketing, including a broader use of targeted post-approval studies, institution of active and sentinel event surveillance, and data mining of available drug utilization databases; (3) monitor the design and implementation of any independent drug safety board that may be instituted within the FDA, or external to the agency, and respond as appropriate; and (4) support adequate funding to implement an improved FDA postmarketing prescription drug surveillance process. (CSA Rep. 6, A-05 Modified: CSAPH Rep. 1, A-15)

#### **H-100.992, “FDA”**

(1) Our AMA reaffirms its support for the principles that: (a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute; (b) this evidence should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies; and (c) any risk/benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.

(2) The AMA believes that social and economic concerns and disputes per se should not be permitted to play a significant part in the FDA's decision-making process in the course of FDA devising either general or product specific drug regulation.

(3) It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history. (Res. 119, A-80 Reaffirmed: CLRPD Rep. B, I-90 Reaffirmed: Sunset Report, I-00 Reaffirmation A-06 Appended: Sub. Res. 509, A-06 Reaffirmation I-07 Reaffirmation I-09 Reaffirmation I-10)

#### **H-110.986, “Incorporating Value into Pharmaceutical Pricing”**

1. Our AMA supports value-based pricing programs, initiatives and mechanisms for pharmaceuticals that are guided by the following principles: (a) value-based prices of pharmaceuticals should be determined by objective, independent entities; (b) value-based prices of pharmaceuticals should be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes; (c) processes to determine value-based prices of pharmaceuticals

must be transparent, easily accessible to physicians and patients, and provide practicing physicians and researchers a central and significant role; (d) processes to determine value-based prices of pharmaceuticals should limit administrative burdens on physicians and patients; (e) processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help assure patient affordability as well as limit system-wide budgetary impact; and (f) value-based pricing of pharmaceuticals should allow for patient variation and physician discretion.

2. Our AMA supports the inclusion of the cost of alternatives and cost-effectiveness analysis in comparative effectiveness research.

3. Our AMA supports direct purchasing of pharmaceuticals used to treat or cure diseases that pose unique public health threats, including hepatitis C, in which lower drug prices are assured in exchange for a guaranteed market size. (CMS Rep. 05, I-16 Reaffirmed in lieu of: Res. 207, A-17 Reaffirmed: CMS-CSAPH Rep. 01, A-17 Reaffirmed: CMS Rep. 07, A-18)

#### **H-120.958, “Supporting Safe Medical Products as a Priority Public Health Initiative”**

Our AMA will: (1) work through the United States Adopted Names (USAN) Council to adopt methodology to help prevent "look alike-sound alike" errors in giving new drugs generic names;

(2) continue participation in the National Patient Safety Foundation's efforts to advance the science of safety in the medication use process and likewise work with the National Coordinating Council for Medication Error Reporting and Prevention;

(3) support the FDA's Medwatch program by working to improve physicians' knowledge and awareness of the program and encouraging proper reporting of adverse events;

(4) vigorously work to support and encourage efforts to create and expeditiously implement a national machine-readable coding system for prescription medicine packaging in an effort to improve patient safety;

(5) participate in and report on the work of the Healthy People 2010 initiative in the area of safe medical products especially as it relates to existing AMA policy; and

(6) seek opportunities to work collaboratively within the Medicine-Public Health initiative

(H-440.991) and with the Food and Drug Administration (FDA), National Institutes of Health (NIH), United States Pharmacopoeia (USP) and Centers for Disease Control and Prevention (CDC) the Agency for Health Care Policy and Research (AHCPR) and the Centers for Medicare & Medicaid Services (CMS) to provide information to individual physicians and state medical societies on the need for public health infrastructure and local consortiums to work on problems related to medical product safety. (Res. 416, A-99 Appended: Res. 504, I-01 Reaffirmation A-10)

#### **H-315.973, “Guiding Principles for the Collection, Use and Warehousing of Electronic Medical Records and Claims Data”**

1. It is AMA policy that any payer, clearinghouse, vendor, or other entity that collects and uses electronic medical records and claims data adhere to the following principles: a. Electronic medical records and claims data transmitted for any given purpose to a third party must be the minimum necessary needed to accomplish the intended purpose. b. All covered entities involved in the collection and use of electronic medical records and claims data must comply with the HIPAA Privacy and Security Rules. c. The physician must be informed and provide permission for any analysis undertaken with his/her electronic medical records and claims data, including the data being studied and how the results will be used. d. Any additional work required by the physician practice to collect data beyond the average data collection for the submission of transactions (e.g., claims, eligibility) must be compensated by the entity requesting the data. e. Criteria developed for the analysis of physician claims or medical record data must be open for review and input by relevant outside entities. f. Methods and criteria for analyzing the electronic medical records and claims data must be provided to the physician or an independent third party so re-analysis of the data can be performed. g. An appeals process must be in place for a physician to appeal, prior to public release, any adverse decision derived from an analysis of his/her electronic medical records and claims data. h. Clinical data collected by a data exchange network and searchable by a record locator service must be accessible only for payment and health care operations.

2. It is AMA policy that any physician, payer, clearinghouse, vendor, or other entity that warehouses electronic medical records and claims data adhere to the following principles: a. The warehouse vendor must take the necessary steps to ensure the confidentiality, integrity, and availability of electronic medical records and claims data while protecting against threats to the security or integrity and unauthorized uses or disclosure of the information. b. Electronic medical records data must remain accessible to authorized users

for purposes of treatment, public health, patient safety, quality improvement, medical liability defense, and research. c. Physician and patient permission must be obtained for any person or entity other than the physician or patient to access and use individually identifiable clinical data, when the physician is specifically identified. d. Following the request from a physician to transfer his/her data to another data warehouse, the current vendor must transfer the electronic medical records and claims data and must delete/destroy the data from its data warehouse once the transfer has been completed and confirmed. (CMS Rep. 6, I-06 Reaffirmed: BOT Rep. 17, A-13)

#### **D-315.984, "Ownership of Claims Data"**

Our AMA will: (1) encourage physicians to include language designed to buttress rights associated with claims data ownership and access when contracting with health plan payers and other third parties; (2) continue to educate physicians on providing public and private health plan payers the "minimum necessary," as defined in the Health Insurance Portability and Accountability Act (HIPAA) of 1996 and regulations thereunder, protected health information necessary to achieve the purpose of a disclosure; (3) assist physicians wishing to register a complaint against health plan payers that have used claims data to form a database, or that have permitted access to or sale of the database or its contents without explicit patient and/or physician authorization, beyond the scope permitted by HIPAA with the Department of Health and Human Services Office of Civil Rights; (4) advocate to the Department of Health and Human Services, Office of the National Coordinator of Health Information Technology and/or other appropriate agencies for rules and regulations ensuring appropriate physician ownership and access rights to claims data, and appropriate protection of claims data held by various parties; and (5) continue to monitor federal and state activities impacting the exchange of physician-generated health information, including claims data. (BOT Rep. 19, I-06 Modified: CCB/CLRPD Rep. 2, A-14)

#### **H-406.987, "Medical Information and Its Uses"**

##### **DATA TRANSPARENCY PRINCIPLES TO PROMOTE IMPROVEMENTS IN QUALITY AND CARE DELIVERY**

Our AMA seeks to help physicians improve the quality reporting of patient care data and adapt to new payment and delivery models to transform our health care system. One means of accomplishing this goal is to increase the transparency of health care data. The principles outlined below ensure that physicians, practices, care systems, physician-led organizations, patients and other relevant stakeholders can access and proactively use meaningful, actionable health care information to achieve care improvements and innovations. These principles do not replace but build upon existing AMA policies H-406.990, H-406.989, H-406.991, and H-406.996 that address safeguards for the release of physician data and physician profiles, expanding these guidelines to reflect the new opportunities and potential uses of this information.

##### **Transparency Objectives and Goals**

**Engaging Physicians** - Our AMA encourages greater physician engagement in transparency efforts, including the development of physician-led quality measures to ensure that gaps in measures are minimized and that analyses reflect the knowledge and expertise of physicians.

**Promoting New Payment and Delivery Models** - Our AMA supports appropriate funding and other support to ensure that the data that are used to inform new payment and delivery models are readily available and do not impose a new cost or additional burden on model participants.

**Improving Care Choices and Decisions** - Our AMA promotes efforts to present data appropriately depending on the objective and the relevant end-user, including transparently identifying what information is being provided, for what purpose, and how the information can or cannot be used to influence care choices.

**Informing Physicians** - Our AMA encourages the development of user interfaces that allow physicians or their staff to structure simple queries to obtain and track actionable reports related to specific patients, peer comparisons, provider-level resource use, practice patterns, and other relevant information.

**Informing Patients** - Our AMA encourages patients to consult with physicians to understand and navigate health care transparency and data efforts.

**Informing Other Consumers** - Our AMA seeks opportunities to engage with other stakeholders to facilitate physician involvement and more proactive use of health care data.

##### **Data Transparency Resources**

**Data Availability** - Our AMA supports removing barriers to accessing additional information from other payers and care settings, focusing on data that is valid, reliable, and complete.



**Access to Timely Data** - While some datasets will require more frequent updates than others, our AMA encourages use of the most current information and that governmental reports are made available, at a minimum, from the previous quarter.

**Accurate Data** - Our AMA supports proper oversight of entities accessing and using health care data, and more stringent safeguards for public reporting, so that information is accurate, transparent, and appropriately used.

**Use of Quality Data** - Our AMA supports definitions of quality based on evidence-based guidelines, measures developed and supported by specialty societies, and physician-developed metrics that focus on patient outcomes and engagement.

**Increasing Data Utility** - Our AMA promotes efforts by clinical data registries, regional collaborations, Qualified Entities, and specialty societies to develop reliable and valid performance measures, increase data utility and reduce barriers that currently limit access to and use of the health care data.

**Challenges to Transparency**

**Standardization** - Our AMA supports improvements in electronic health records (EHRs) and other technology to capture and access data in uniform formats.

**Mitigating Administrative Burden** - To reduce burdens, data reporting requirements imposed on physicians should be limited to the information proven to improve clinical practice. Collection, reporting, and review of all other data and information should be voluntary.

**Data Attribution** - Our AMA seeks to ensure that those compiling and using the data avoid attribution errors by working to correctly assign services and patients to the appropriate provider(s) as well as allowing entities to verify who or where procedures, services, and items were performed, ordered, or otherwise provided. Until problems with the current state of episode of care and attribution methodologies are resolved, our AMA encourages public data and analyses primarily focused at the system-level instead of on individual physicians or providers. (BOT Rep. 6, A-15)

#### **H-406.989, “Work of the Task Force on the Release of Physician Data”**

1. Our AMA Council on Legislation will use the Release of Claims and Payment Data from Governmental Programs as a basis for draft model legislation. 2. Our AMA will create additional tools to assist physicians in dealing with the release of physician data. 3. Our AMA will continue to monitor the status of, and take appropriate action on, any legislative or regulatory opportunities regarding the appropriate release and use of physician data and its use in physician profiling programs. 4. Our AMA will monitor new and existing Web sites and programs that collect and use data on patient satisfaction and take appropriate action when safeguards are not in place to ensure the validity of the results. 5. Our AMA will continue and intensify its extensive efforts to educate employers, healthcare coalitions and the public about the potential risks and liabilities of pay-for-performance and public reporting programs that are not consistent with AMA policies, principles, and guidelines. 6. Our AMA: A) opposes the public reporting of individual physician performance data collected by certification and licensure boards for purposes of MOC and MOL; and B) supports the principle that individual physician performance data collected by certification and licensure boards should only be used for the purposes of helping physicians to improve their practice and patient care, unless specifically approved by the physician. (BOT Rep. 18, A-09 Reaffirmed: BOT action in response to referred for decision Res. 709, A-10, Res. 710, A-10, Res. 711, A-10 and BOT Rep. 17, A-10 Reaffirmed in lieu of Res. 808, I-10 Appended: Res. 327, A-11 Modified: CCB/CLRPD Rep. 2, A-14)

#### **H-406.990, “Work of the Task Force on the Release of Physician Data”**

**Release of Claims and Payment Data from Governmental Programs**

The AMA encourages the use of physician data to benefit both patients and physicians and to improve the quality of patient care and the efficient use of resources in the delivery of health care services. The AMA supports this use of physician data only when it preserves access to health care and is used to provide accurate physician performance assessments.

Raw claims data used in isolation have significant limitations. The release of such data from government programs must be subject to safeguards to ensure that neither false nor misleading conclusions are derived that could undermine the delivery of appropriate and quality care. If not addressed, the limitations of such data are significant. The foregoing limitations may include, but are not limited to, failure to consider factors that impact care such as specialty, geographic location, patient mix and demographics, plan design, patient compliance, drug and supply costs, hospital and service costs, professional liability coverage, support staff and other practice costs as well as the potential for mistakes and errors in the data or its attribution.

Raw claims and payment data resulting from government health care programs, including, but not limited to, the Medicare and Medicaid programs should only be released:

1. when appropriate patient privacy is preserved via de-identified data aggregation or if written authorization for release of individually identifiable patient data has been obtained from such patient in accordance with the requirements of the Health Insurance Portability and Accountability Act (HIPAA) and applicable regulations;
  2. upon request of physicians [or their practice entities] to the extent the data involve services that they have provided;
  3. to law enforcement and other regulatory agencies when there is reasonable and credible reason to believe that a specific physician [or practice entity] may have violated a law or regulation, and the data is relevant to the agency's investigation or prosecution of a possible violation;
  4. to researchers/policy analysts for bona fide research/policy analysis purposes, provided the data do not identify specific physicians [or their practice entities] unless the researcher or policy analyst has (a) made a specific showing as to why the disclosure of specific identities is essential; and, (b) executed a written agreement to maintain the confidentiality of any data identifying specific physicians [or their practice entities];
  5. to other entities only if the data do not identify specific physicians [or their practice entities]; or
  6. if a law is enacted that permits the government to release raw physician-specific Medicare and/or Medicaid claims data, or allows the use of such data to construct profiles of identified physicians or physician practices. Such disclosures must meet the following criteria: (a) the publication or release of this information is deemed imperative to safeguard the public welfare; (b) the raw data regarding physician claims from governmental healthcare programs is: (i) published in conjunction with appropriate disclosures and/or explanatory statements as to the limitations of the data that raise the potential for specific misinterpretation of such data. These statements should include disclosure or explanation of factors that influence the provision of care including geographic location, specialty, patient mix and demographics, health plan design, patient compliance, drug and supply costs, hospital and service costs, professional liability coverage, support staff and other practice costs as well as the potential for mistakes and errors in the data or its attribution, in addition to other relevant factors. (ii) safeguarded to protect against the dissemination of inconsistent, incomplete, invalid or inaccurate physician-specific medical practice data.
- (c) any physician profiling which draws upon this raw data acknowledges that the data set is not representative of the physicians' entire patient population and uses a methodology that ensures the following: (i) the data are used to profile physicians based on quality of care provided - never on utilization of resources alone - and the degree to which profiling is based on utilization of resources is clearly identified. (ii) data are measured against evidence-based quality of care measures, created by physicians across appropriate specialties. (iii) the data and methodologies used in profiling physicians, including the use of representative and statistically valid sample sizes, statistically valid risk-adjustment methodologies and statistically valid attribution rules produce verifiably accurate results that reflect the quality and cost of care provided by the physicians. (d) any governmental healthcare data shall be protected and shared with physicians before it is released or used, to ensure that physicians are provided with an adequate and timely opportunity to review, respond and appeal the accuracy of the raw data (and its attribution to individual physicians) and any physician profiling results derived from the analysis of physician-specific medical practice data to ensure accuracy prior to their use, publication or release. (BOT Rep. 18, A-09 Reaffirmed: BOT Rep. 09, A-19 Modified: Speakers Rep., A-19)

#### **H-406.991, "Work of the Task Force on the Release of Physician Data"**

##### **Principles for the Public Release and Accurate Use of Physician Data**

The AMA encourages the use of physician data to benefit both patients and physicians and to improve the quality of patient care and the efficient use of resources in the delivery of health care services. The AMA supports this use of physician data when it is used in conjunction with program(s) designed to improve or maintain the quality of, and access to, medical care for all patients and is used to provide accurate physician performance assessments in concert with the following Principles:

1. Patient Privacy Safeguards
  - All entities involved in the collection, use and release of claims data comply with the HIPAA Privacy and Security Rules (H-315.972, H-315.973, H-315.983, H-315.984, H-315.989, H-450.947).

- Disclosures made without patient authorization are generally limited to claims data, as that is generally the only information necessary to accomplish the intended purpose of the task (H-315.973, H-315.975, H-315.983).

## 2. Data Accuracy and Security Safeguards

- Effective safeguards are established to protect against the dissemination of inconsistent, incomplete, invalid or inaccurate physician-specific medical practice data (H-406.996, H-450.947, H-450.961).
- Reliable administrative, technical, and physical safeguards provide security to prevent the unauthorized use or disclosure of patient or physician-specific health care data and physician profiles (H-406.996, H-450.947, H-450.961).
- Physician-specific medical practice data, and all analyses, proceedings, records and minutes from quality review activities are not subject to discovery or admittance into evidence in any judicial or administrative proceeding without the physician's consent (H-406.996, H-450.947, H-450.961).

## 3. Transparency Requirements

- When data are collected and analyzed for the purpose of creating physician profiles, the methodologies used to create the profiles and report the results are developed in conjunction with relevant physician organizations and practicing physicians and are disclosed in sufficient detail to allow each physician or medical group to re-analyze the validity of the reported results prior to more general disclosure (H-315.973, H-406.993, H-406.994, H-406.998, H-450.947, H-450.961).
- The limitations of the data sources used to create physician profiles are clearly identified and acknowledged in terms understandable to consumers (H-406.994, H-450.947).
- The capabilities and limitations of the methodologies and reporting systems applied to the data to profile and rank physicians are publicly revealed in understandable terms to consumers (H-315.973, H-406.994, H-406.997, H-450.947, H-450.961).
- Case-matched, risk-adjusted resource use data are provided to physicians to assist them in determining their relative utilization of resources in providing care to their patients (H-285.931).

## 4. Review and Appeal Requirements

- Physicians are provided with an adequate and timely opportunity to review, respond and appeal the results derived from the analysis of physician-specific medical practice data to ensure accuracy prior to their use, publication or release (H-315.973, H-406.996, H-406.998, H-450.941, H-450.947, H-450.961).
- When the physician and the rater cannot reach agreement, physician comments are appended to the report at the physician's request (H-450.947).

## 5. Physician Profiling Requirements

- The data and methodologies used in profiling physicians, including the use of representative and statistically valid sample sizes, statistically valid risk-adjustment methodologies and statistically valid attribution rules produce verifiably accurate results that reflect the quality and cost of care provided by the physicians (H-406.994, H-406.997, H-450.947, H-450.961).
- Data reporting programs only use accurate and balanced data sources to create physician profiles and do not use these profiles to create tiered or narrow network programs that are used to steer patients towards certain physicians primarily on cost of care factors (450.951).
- When a single set of claims data includes a sample of patients that are skewed or not representative of the physicians' entire patient population, multiple sources of claims data are used.
- Physician efficiency of care ratings use physician data for services, procedures, tests and prescriptions that are based on physicians' patient utilization of resources so that the focus is on comparative physicians' patient utilization and not on the actual charges for services.
- Physician-profiling programs may rank individual physician members of a medical group but do not use those individual rankings for placement in a network or for reimbursement purposes.

## 6. Quality Measurement Requirements

- The data are used to profile physicians based on quality of care provided - never on utilization of resources alone -- and the degree to which profiling is based on utilization of resources is clearly identified (H-450.947).
- Data are measured against evidence-based quality of care measures, created by physicians across appropriate specialties, such as the Physician Consortium for Performance Improvement. (H-406.994, H-406.998, H-450.947, H-450.961).
- These evidence-based measures are endorsed by the National Quality Forum (NQF) and/or the AQA and HQA, when available. When unavailable, scientifically valid measures developed in conjunction with appropriate medical specialty societies and practicing physicians are used to evaluate the data.

#### 7. Patient Satisfaction Measurement Requirements

- Until the relationship between patient satisfaction and other outcomes is better understood, data collected on patient satisfaction is best used by physicians to better meet patient needs particularly as they relate to favorable patient outcomes and other criteria of high quality care (H-450.982).
- Because of the difficulty in determining whether responses to patient satisfaction surveys are a result of the performance of a physician or physician office, or the result of the demands or restrictions of health insurers or other factors out of the control of the physician, the use of patient satisfaction data is not appropriate for incentive or tiering mechanisms.
- As in physician profiling programs, it is important that programs that publicly rate physicians on patient satisfaction notify physicians of their rating and provide a chance for the physician to appeal that rating prior to its publication. (BOT Rep. 18, A-09 Reaffirmation A-10 Reaffirmed: BOT action in response to referred for decision Res. 709, A-10, Res. 710, A-10, Res. 711, A-10 and BOT Rep. 17, A-10 Reaffirmation I-10 Reaffirmed in lieu of Res. 808, I-10 Reaffirmed in lieu of Res. 824, I-10 Reaffirmation A-11 Reaffirmed: BOT Rep. 17, A-13 Reaffirmed: Res. 806, I-13 Reaffirmation: A-19)

#### **H-406.996, “Use and Release of Physician-Specific Health Care Data”**

- (1) Our AMA advocates that third party payers, government entities and others that use and release physician-specific health care data adhere to the following principles: (a) Physicians under review and relevant physician organizations shall be provided with an adequate opportunity to review and respond to proposed physician-specific health care data interpretations and disclosures prior to their publication or release. (b) Effective safeguards to protect against the dissemination of inconsistent, incomplete, invalid, inaccurate or subjective physician-specific health care data shall be established. (c) Reliable administrative, technical, and physical safeguards to prevent the unauthorized use or disclosure of physician-specific health care data shall be developed. (d) Such safeguards shall treat all underlying physician-specific health care data and all analyses, proceedings, records, and minutes from quality review activities on physician-specific health care data as confidential, and provide that none of these documents shall be subject to discovery, or admitted into evidence in any judicial or administrative proceeding.
- (2) Our AMA supports release of severity-adjusted physician-specific health care data from carefully selected pilot projects where the data may be deemed accurate, reliable, and meaningful to physicians, consumers, and purchaser;
- (3) Our AMA urges that any published physician-specific health care data be limited to appropriate data concerning the quality of health care, access to health care, and the cost of health care;
- (4) Our AMA opposes the publication of physician-specific health care data collected outside of carefully selected pilot studies or where the data are not deemed accurate, reliable, or meaningful;
- (5) Our AMA urges that a copy of the information in any such profile be forwarded to the subject physician, and that the physician be given the right to review and certify adequacy of the information prior to any profile being distributed, including being placed on the Internet; and
- (6) Our AMA urges that the costs associated with creation of any such profiling system should not be paid for by physicians licensure fees. (BOT Rep. Q, I-92 BOT Rep. W, A-92 Reaffirmed: Res. 719, A-93 CMS Rep. 10, A-96 Appended: Res. 316, I-97 Reaffirmation A-01 Reaffirmation A-02 Reaffirmation A-05 Reaffirmed in lieu of Res. 724, A-05 Reaffirmed: BOT action in response to referred for decision Res. 709, A-10, Res. 710, A-10, Res. 711, A-10 and BOT Rep. 17, A-10)

#### **H-406.999, “Goal of Health Care Data Collection”**

The AMA (1) continues to advocate that health care data collected by government and third party payers be used for education of both consumers and providers; and (2) believes that government, third party payers and self-insured companies should make physician-specific utilization information available to medical societies. (BOT Rep. W, A-92 Reaffirmed: Res. 719, A-93 BOT Rep. Y, I-85 Reaffirmed CLRPD Rep. 2, I-95 CMS Rep. 10, A-96 Reaffirmed: CMS Rep. 8, A-06 Reaffirmed: CMS Rep. 01, A-16)

#### **H-410.948, “Clinical Pathways”**

Our AMA supports the development of transparent, collaboratively constructed clinical pathways that: (1) are implemented in ways that promote administrative efficiencies for both providers and payers; (2) promote access to evidence-based care for patients; (3) recognize medical variability among patients and individual patient autonomy; (4) promote access to clinical trials; and (5) are continuously updated to reflect the rapid development of new scientific knowledge. (Res. 708, A-16 Reaffirmed: CMS Rep. 06, A-18)

**H-450.933, “Clinical Data Registries”**

1. Our AMA encourages multi-stakeholder efforts to develop and fund clinical data registries for the purpose of facilitating quality improvements and research that result in better health care, improved population health, and lower costs.
2. Our AMA encourages national medical specialty societies, state medical associations, and other physician groups to join the National Quality Registry Network and to participate in efforts to advance the development and use of clinical data registries.
3. Our AMA supports flexibility in the development and implementation of clinical data registries. The following guidelines can help maximize opportunities for clinical data registries to enhance the quality of care provided to patients: a. Practicing physicians must be actively involved in decisions related to the development, maintenance and use of clinical data registries and registry data. b. Data elements, risk-adjustment models and measures used in the registry should be fully transparent. c. Registries should provide timely, actionable feedback reports to individual physicians or entities reporting at the organizational level. d. Registries and electronic health records should be interoperable, and should be capable of sharing and integrating information across registries and with other data sources in a HIPAA-compliant and confidential manner. e. Registry stewards should establish a formal process to facilitate the modification, expansion, or dissolution of the registry in order to accommodate advances in technology and changing clinical data needs to ensure continued utility of their registry.
4. Our AMA encourages physicians to participate in clinical data registries, and will encourage efforts that help physicians identify existing registries suitable for and of benefit to their patient populations and their practices.
5. Our AMA will continue to advocate for and support initiatives that minimize the costs and maximize the benefits of physician practice participation in clinical data registries.
6. Our AMA supports that, with the consent of the participating physician, physician-specific clinical registry data may be used to meet third-party quality reporting requirements, in accordance with the following principles: a. Data should be used to improve the quality of patient care and the efficient use of resources in the delivery of health care services. b. Data related to resource use and cost of care must be evaluated and reported in conjunction with quality of care information. c. Effective safeguards must be established to protect against the dissemination of inconsistent, incomplete, invalid or inaccurate physician-specific medical practice data. d. Case-matched, risk-adjusted quality measure and resource use data are provided to physicians to assist them in determining their relative utilization of resources in providing care to their patients. e. When data are collected and analyzed for the purpose of meeting quality reporting requirements, the methodologies used to create the profiles and report the results are developed in conjunction with relevant physician organizations and practicing physicians, and are disclosed in sufficient detail to allow each physician or medical group to re-analyze the validity of the reported results prior to more general disclosure. (CMS Rep. 8, A-14 Reaffirmed: CMS Rep. 05, I-16 Reaffirmed: CMS Rep. 10, A-17)

**H-460.926, “Funding of Biomedical, Translational, and Clinical Research”**

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

**H-460.943, “Potential Impact of Health System Reform Legislative Reform Proposals on Biomedical Research and Clinical Investigation”**

The AMA, to encourage and support the continuing development of new advances in science and medicine and the development and implementation of meaningful quality assurance programs essential to improving the delivery of medical and health care in the United States, advocates:

- (1) Strong support and funding for medical education programs at all levels to attract and stimulate gifted students and physicians to receive training and experience in, and to participate in, basic science or clinically-oriented research programs.
- (2) Strong financial and policy support for all aspects of biomedical science and research, including: basic science research (investigator initiated grant-funded research) in a wide variety of fields; laboratory-based

clinical studies (including surgical studies); clinical studies and therapy trials; clinical outcomes research; behavioral science research, including studies to assess implementation of health promotion and/or disease prevention activities; and technology transfer research, with an emphasis on diffusing information about, training personnel in, and encouraging appropriate use of new technologies.

(3) Adequate federal funding for biomedical science programs, including an appropriate balance of funding for basic, clinical, health service, and public health/prevention research.

(4) Support and funding for evaluation and implementation research, including drug and technology assessment, medical device review, and developing and setting standards for computerized medical records. (CSA Rep. 10, A-94 Reaffirmed: CSA Rep. 8, A-05 Reaffirmed: CSAPH Rep. 1, A-15)

#### **D-460.970, “Access to Clinical Trial Data”**

Our AMA: (1) urges the Food and Drug Administration to investigate and develop means by which scientific investigators can access original source safety data from industry-sponsored trials upon request; and (2) supports the adoption of universal policy by medical journals requiring participating investigators to have independent access to all study data from industry-sponsored trials. (Res. 503, A-14 Reaffirmed: Res. 907, I-15)

#### **D-460.972, “Creation of a National Registry for Healthy Subjects in Phase I Clinical Trials”**

Our AMA encourages the development and implementation of a national registry, with minimally identifiable information, for healthy subjects in Phase I trials by the US Food and Drug Administration or other appropriate organizations to promote subject safety, research quality, and to document previous trial participation. (Res. 913, I-11)

#### **H-525.991, “Inclusion of Women in Clinical Trials”**

Our AMA: (1) encourages the inclusion of women, including pregnant women when appropriate, in all research on human subjects, except in those cases for which it would be scientifically irrational, in numbers sufficient to ensure that results of such research will benefit both men and women alike; (2) supports the National Institutes of Health policy requiring investigators to account for the possible role of sex as a biological variable in vertebrate animal and human studies; and (3) encourages translation of important research results into practice. (Res. 183, I-90 Reaffirmed: Sunset Report, I-00 Reaffirmed: CSAPH Rep. 1, A-10 Modified: CSAPH Rep. 05, A-16 Reaffirmed: Res. 909, I-16)

### **8.8 Required Reporting of Adverse Events**

Physicians’ professional commitment to advance scientific knowledge and make relevant information available to patients, colleagues, and the public carries with it the responsibility to report suspected adverse events resulting from the use of a drug or medical device.

Mandated pre- and post-marketing studies provide basic safeguards for public health, but are inherently limited in their ability to detect rare or unexpected consequences of use of a drug or medical device. Thus spontaneous reports of adverse events, especially rare or delayed effects or effects in vulnerable populations are irreplaceable as a source of information about the safety of drugs and devices. As the professionals who prescribe and monitor the use of drugs and medical devices, physicians are best positioned to observe and communicate about adverse events.

Cases in which there is clearly a causal relationship between use of a drug/device and an adverse event, especially a serious event, will be rare. Physicians need not be certain that there is such an event, or even that there is a reasonable likelihood of a causal relationship, to suspect that an adverse event has occurred. A physician who suspects that an adverse reaction to a drug or medical device has occurred has an ethical responsibility to: (a) Communicate that information to the professional community through established reporting mechanisms. (b) Promptly report serious adverse events requiring hospitalization, death, or medical or surgical intervention to the appropriate regulatory agency.

AMA Principles of Medical Ethics: I,V,VII

Issued: 2016

# REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 3-I-19

Subject: Patient Use of Non-FDA Approved Cannabis and Cannabinoid Products in Hospitals (Resolution 414-A-19)

Presented by: Michael M. Miller, MD, Chair

Referred to: Reference Committee K

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Resolution 414-A-19, introduced by the Oklahoma Delegation and referred by the House of Delegates asks:

That our American Medical Association offer guidance to medical staffs regarding patient use of non-US Food and Drug Administration approved medical marijuana and cannabinoids on hospital property, including product use, storage in patient rooms, nursing areas and/or pharmacy, with report back to the House of Delegates at the 2019 Interim Meeting.

## METHODS

English language reports were selected from searches of the PubMed and Google Scholar databases from January 2009 to August 2019 using the search terms: “hospital policies” and cannabis; “hospital policies” and marijuana. Additional articles were identified by manual review of the reference lists of pertinent publications. Web sites managed by federal agencies and applicable professional organizations, including hospital associations, were reviewed for relevant information.

The Council on Science and Public Health acknowledges that the use of non-FDA approved cannabis and cannabinoid products presents challenges in health care facilities beyond hospitals (e.g., long-term care facilities, mental health and addiction facilities) and patients (e.g., visitors and employees), but those issues were deemed outside of the scope of this report.

## CURRENT AMA POLICY

The AMA 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. Furthermore, cannabis for medicinal use should not be legalized through the state legislative, ballot initiative, or referendum process. The AMA also 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 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 (D-95.969, “Cannabis Legalization for Medicinal Use”).

The 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-

1 based medical cannabis programs, the legalization of cannabis, or that scientific evidence on the  
2 therapeutic use of cannabis meets the current standards for a prescription drug product (H-95.952,  
3 “Cannabis and Cannabinoid Research”).

#### 4 5 STATUS OF CANNABIS UNDER FEDERAL LAW

6  
7 Under the U.S. Controlled Substances Act (CSA) of 1970, cannabis is classified as a Schedule I  
8 controlled substance, meaning it has no currently accepted medical use in treatment in the United  
9 States, a lack of accepted safety for use under medical supervision, and a high potential for abuse.<sup>1</sup>  
10 This means that the cultivation, manufacture, sale distribution, and use of medical cannabis violates  
11 the CSA and constitutes a federal felony.

12  
13 Cannabis is not FDA-approved as a safe and effective drug for any indication. However, the  
14 agency has approved three drug products containing synthetic versions of the main psychoactive  
15 ingredient of cannabis, delta-9 tetrahydrocannabinol (THC). Marinol® and Syndros™, which  
16 include the active ingredient dronabinol, are indicated for nausea and vomiting associated with  
17 cancer chemotherapy and anorexia associated with weight loss in patients with AIDS.<sup>3</sup> Cesamet®,  
18 which contains the active ingredient nabilone, is also indicated for the treatment of the nausea and  
19 vomiting associated with cancer chemotherapy.<sup>2</sup>

20  
21 The Agriculture Improvement Act of 2018 (Farm Bill) removed hemp from the CSA, which means  
22 that cannabis plants and derivatives that contain no more than 0.3 percent THC on a dry weight  
23 basis are no longer controlled substances under federal law.<sup>2</sup> However, the law explicitly preserved  
24 FDA’s authority to regulate products containing cannabis or cannabis-derived compounds.<sup>2</sup> The  
25 FDA has approved one cannabis-derived product, Epidiolex®, which contains a purified form of  
26 the drug substance cannabidiol (CBD) for the treatment of seizures associated with Lennox-Gastaut  
27 or Dravet syndrome.<sup>3</sup> The FDA has expressed concern at the proliferation of products asserting to  
28 contain CBD that are being marketed for therapeutic or medical uses that have not been approved  
29 by FDA.<sup>3</sup> Since CBD has been studied as a new drug, it cannot be legally included in foods or  
30 dietary supplements. The FDA is currently considering potential regulatory frameworks for CBD.

#### 31 32 STATUS OF CANNABIS UNDER STATE LAW

33  
34 At the state level, trends in law have moved from decriminalization, to the legalization of medical  
35 use of cannabis, to cannabis regulated for adult use.<sup>4</sup> California was the first jurisdiction in the  
36 United States to legalize the medical use of cannabis. Today, 33 states, the District of Columbia,  
37 Guam, Puerto Rico, and the U.S. Virgin Islands have legalized the medical use of cannabis through  
38 either the legislative process or ballot measures. These laws vary greatly by jurisdiction, from how  
39 patients access the product (home cultivated or dispensary), to qualifying conditions, product safety  
40 and testing requirements, packaging and labeling requirements, and consumption method (some  
41 states prohibit smoking the product). In jurisdictions that have legalized cannabis for medicinal use,  
42 physicians can “certify” or “recommend” a qualifying patient for the medicinal use of cannabis, but  
43 physicians cannot prescribe cannabis for medical purposes because it is illegal under federal law. In  
44 recent years, an additional 17 states have enacted laws allowing access to low THC/high CBD  
45 products for children with epilepsy.

46  
47 In 2012, Colorado and Washington were the first U.S. jurisdictions to legalize the adult use of  
48 cannabis for recreational purposes. Today, a total of 11 states and the District of Columbia have  
49 legalized cannabis for adult use. Most of these jurisdictions have created for-profit, commercial  
50 cannabis production and distribution markets where the product is sold and taxed.



## DISCUSSION

The AMA does not approve of state-based medical cannabis programs, the legalization of cannabis, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product. Hospitals are being encouraged to accommodate patient use of cannabis.<sup>5</sup> The primary argument for allowing patients to use cannabis in hospitals is focused on continuity of care. If patients have had success using cannabis for medicinal purposes, ending that treatment due to a hospital admission disrupts treatment and could lead to worse outcomes.<sup>5</sup>

### *Risks to Hospitals in Allowing Patient Use of Cannabis Products*

Hospitals are subject to federal law because they receive reimbursement from federal programs. Since cannabis is a Schedule 1 controlled substance, its manufacture, distribution, or possession is a criminal offense. Hospitals that allow patient use of cannabis are at risk of violating federal law, losing their deemed status from Centers for Medicare and Medicaid Services (CMS), exposing themselves to possible penalties or sanctions, and losing federal funding.<sup>6-8</sup>

Physicians who maintain DEA licensure are also subject to federal law and are not permitted to prescribe a Schedule I substance. In addition to the prohibition on prescribing, the DEA also prohibits a practitioner from administering a Schedule I substance, which means that physicians and other clinicians with DEA licenses cannot administer cannabis. Doing so may jeopardize a clinician's federal DEA registration and their ability to prescribe controlled substances.

In addition to federal law, hospitals must also meet standards for pharmacies and medication management such as those established by hospital accreditation bodies.<sup>8</sup> For example, The Joint Commission Standard MM.03.01.05 on Medication Management requires that: "[t]he hospital safely controls medications brought into the hospital by patients, their families, or licensed independent practitioners."<sup>8,9</sup>

This standard includes the following elements of performance:

- The hospital defines when medications brought into the hospital by patients, their families, or licensed independent practitioners can be administered.<sup>9</sup>
- Before use or administration of a medication brought into the hospital by a patient, his or her family, or a licensed independent practitioner, the hospital identifies the medication and visually evaluates the medication's integrity.<sup>9</sup>
- The hospital informs the prescriber and patient if the medication brought into the hospital by patients, their families, or licensed independent practitioners is not permitted.<sup>9</sup>

One of the biggest challenges for hospitals in meeting this standard for cannabis would likely be identifying the medication and visually evaluating the medication's integrity.<sup>8</sup> Depending on state law, the patient may be enrolled in the state's cannabis for "medicinal use" program and have their own supply from a state licensed manufacturer. However, the hospital would likely not want to assume responsibility for vetting the substance or any adverse effects the patient experiences as a result of the product.

Hospitals would also have to address medication storage concerns, particularly if cannabis products should be stored with the pharmacy department and treated as a controlled substance, by security personnel, or with the patient.<sup>10</sup> There are also complicated logistics for self-administration of cannabis by the patient or caregiver. Many hospitals have policies on self-administration of

1 medicines that permit patients to use their own medications only after identification and labeling by  
2 pharmacy personnel.

3  
4 Since many hospitals have policies prohibiting smoking on facility grounds, hospitals would have  
5 to determine what preparations of cannabis would be allowed (e.g., oils or edibles).<sup>8</sup> Hospitals  
6 should also be prepared to provide information to their medical staffs on cannabis withdrawal  
7 symptoms as well as possible cannabis or cannabinoid contraindications, drug interactions, or  
8 possible adverse effects.

### 9 10 *State Laws Addressing Cannabis Use in Hospitals*

11  
12 Some states have tried to address cannabis use in hospital facilities by amending their state laws.  
13 Connecticut and Maine permit the use of cannabis by hospitalized patients and give some state-  
14 level legal protection for clinicians who administer it. Connecticut law provides that a nurse shall  
15 not be subject to arrest or prosecution, or penalized in any manner for administering cannabis to a  
16 qualifying patient or research program subject in a hospital or health care facility licensed by the  
17 Department of Public Health.<sup>11</sup>

18  
19 Maine has enacted protection for hospitals and long-term care facilities for use of edible cannabis  
20 products, tinctures, and salves by an admitted patient who has been certified for use of cannabis  
21 products under state law.<sup>12</sup> The law provides that hospitals and long-term care facilities are not  
22 subject to prosecution, search, seizure or penalty in any manner, including but not limited to a civil  
23 penalty or disciplinary action by an occupational or professional licensing board or entity, and may  
24 not be denied any license, registration, right or privilege solely because the admitted patient  
25 lawfully engages in conduct involving the medical use of cannabis.<sup>12</sup> These protections also apply  
26 to officers or directors, employees or agents of a hospital or long-term care facility.<sup>12</sup>

27  
28 Minnesota law provides that hospitals may adopt reasonable restrictions on use and storage of  
29 cannabis.<sup>13</sup> The restrictions may include a provision that the provider will not store or maintain the  
30 patient's supply of cannabis, that the provider is not responsible for providing cannabis for patients,  
31 and that cannabis be used only in a place specified by the provider.<sup>13</sup> Under Minnesota state law,  
32 employees of these facilities are not subject to violations under the statutes for possession while  
33 carrying out employment duties, such as providing or supervising care to a registered patient, or  
34 distribution of cannabis to a registered patient.<sup>14</sup>

35  
36 The Minnesota Hospital Association (MHA) convened a broad group of stakeholders to discuss the  
37 impact of the state's cannabis law on hospital workflows as well as policies and procedures.<sup>15</sup> The  
38 group produced template policies on cannabis for MHA members. The policies can be summarized  
39 as follows: (1) the hospital will not allow patient use of cannabis, (2) the hospital will allow  
40 inpatients to continue use while inpatient in the hospital and cannabis will be treated as self-  
41 administered home therapy, and (3) the hospital will allow inpatients to continue while inpatient in  
42 the hospital and cannabis will be treated as a medication and integrated within the hospital medical  
43 workflows.<sup>15</sup> The templates provide hospitals with a helpful list of issues for consideration.

### 44 45 **CONCLUSION**

46  
47 It is the AMA's position that scientifically valid and well-controlled clinical trials conducted under  
48 federal investigational new drug applications are necessary to assess the safety and effectiveness of  
49 all new drugs, including potential cannabis products for medical use. The AMA does not believe  
50 cannabis for medicinal use should be legalized through the state legislative, ballot initiative, or  
51 referendum process. Given the growing number of states that have legalized cannabis use, hospitals

1 are increasingly likely to encounter patients who are taking cannabis or cannabis-related products.  
2 It has been argued that patients should be allowed to use non-FDA approved cannabis-related  
3 products to ensure continuity of care if they are admitted to the hospital. However, hospitals and  
4 physicians face legal risks in doing so given cannabis' status as a Schedule I controlled substance.  
5 Hospitals should consider the risks associated with allowing the use of non-FDA approved  
6 cannabis or cannabis-derived products by patients and develop policies to address this issue so  
7 patients and clinicians have clarity on what is permitted. Hospitals that decide to allow the use of  
8 non-FDA approved cannabis or cannabis-derived products should provide information to their  
9 medical staffs on cannabis withdrawal symptoms as well as possible cannabis or cannabinoid  
10 contraindications, drug interactions, or possible adverse effects.

## 11 12 RECOMMENDATIONS

13  
14 The Council recommends that the following recommendation be adopted in lieu of Resolution 414-  
15 A-19, and the remainder of the report be filed.

16  
17 The AMA encourages hospitals and health systems to: (1) engage stakeholders, including, but  
18 not limited to physicians, nurses, pharmacists, legal counsel, experts in controlled substance  
19 diversion prevention, as well as relevant state and federal agencies in developing policies for  
20 addressing patient use of non-FDA approved cannabis or cannabis-derived products for use  
21 within their facilities and (2) communicate their policy on patient use of non-FDA approved  
22 cannabis or cannabis-derived products within their facilities, to ensure clinicians are prepared  
23 to treat patients in accordance with policy. (New HOD Policy)

Fiscal Note: less than \$500

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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 901  
(I-19)

Introduced by: Medical Student Section

Subject: Health Impact of Per- and Polyfluoroalkyl Substances (PFAS) Contamination  
in Drinking Water

Referred to: Reference Committee K

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1 Whereas, The Environmental Protection Agency (EPA) determines whether a contaminant  
2 should have an enforceable regulatory standard for water contamination based on three criteria  
3 including: a) adverse effect on the health of persons, b) the contaminant is known to occur in  
4 public water often enough at levels of concern, c) regulation provides a meaningful opportunity  
5 for health risk reductions<sup>1</sup>; and  
6

7 Whereas, Polyfluoroalkyl chemicals (PFAS) are chemicals used in the manufacturing of  
8 thousands of industrial and consumer products and are recognized by the Centers for Disease  
9 Control and Prevention (CDC) as substances toxic to human health<sup>2</sup>; and  
10

11 Whereas, PFAS are non-biodegradable chemicals that accumulate in the human body with  
12 elimination half-lives up to 12 years and as of July 2018 PFAS have been detected at 172 sites  
13 in 40 states and have resulted in more than 3000 environmental and health related publications  
14 since 2000<sup>2-6</sup>; and  
15

16 Whereas, PFAS' negative health effects include but are not limited to increased risk of  
17 hypertension, pre-eclampsia, and low birth weight during pregnancy, endocrine disruption,  
18 increased risk of thyroid and kidney disease, and association with various cancers<sup>2,7,8</sup>; and  
19

20 Whereas, PFAS cross the placental barrier, are detected in cord blood, are transmitted through  
21 breast milk, and are negatively associated with fetal and postnatal growth, immune function, and  
22 reproductive health<sup>9-12</sup>; and  
23

24 Whereas, Children are particularly at risk due to differences in PFAS dosimetry, impact on  
25 physical and cognitive development, and in particular, dose-dependent immunomodulatory  
26 effects which dampen responses to vaccines<sup>9,13,14</sup>; and  
27

28 Whereas, The EPA found PFAS in water and soil nationwide, labeled PFAS an "emerging  
29 contaminant," and in May 2016 released non-enforceable lifetime health advisories for two  
30 specific PFAS chemicals: perfluorooctanoic acid (PFOA) and perfluorooctane sulfonate (PFOS)  
31 of 70 ppt, above this level the EPA recommends that drinking water systems takes steps to  
32 assess contamination, inform consumers, and limit exposure<sup>15,16</sup>; and

1 Whereas, In November 2016, the American Public Health Association stated that all exposures  
2 to PFAS should be reduced, and in June 2018, the CDC's Agency for Toxic Substances and  
3 Disease Registry (ATSDR) recommended reducing the minimum risk levels of PFAS ten-fold,  
4 from 70 ppt to 7 ppt due to the chemicals' significant negative health effects<sup>2,17</sup>; and

5  
6 Whereas, The International Agency for Research on Cancer (IARC), a part of the World Health  
7 Organization (WHO) has classified PFOA as possibly carcinogenic to humans<sup>18</sup>; and

8  
9 Whereas, The EPA sets Maximum Contaminant Level Goals (MCLG) at zero for contaminants  
10 that may cause cancer<sup>1</sup>; and

11  
12 Whereas, The EPA maintains the Integrated Risk Information System (IRIS), an electronic  
13 database that contains information on human health effects from exposure to various  
14 substances in the environment, in which PFOA is not classified as to its carcinogenicity<sup>19,20</sup>; and

15  
16 Whereas, In February 2019, the EPA published its PFAS Action Plan which included as  
17 priorities initiating processes for listing PFOA and PFOS as hazardous substances and  
18 organizing efforts for water supply clean-up, but does not commit to setting maximum  
19 contaminant levels (MCLs)<sup>21,22</sup>; and

20  
21 Whereas, A Congressional PFAS Task Force was established in January 2019 to educate and  
22 draft policies on PFAS based on the latest research, and a Senate bill in March 2019, calls for  
23 PFAS to be designated as a hazardous chemical within a year and require cleanup of  
24 contaminated sites<sup>23,24</sup>; and

25  
26 Whereas, Despite the CDC's recommendations, urging from various U.S. senators, and  
27 examples from various states which have established their own PFAS water guidelines, no  
28 federal PFAS drinking water standards have yet been implemented<sup>16,25-28</sup>; and

29  
30 Whereas, The CDC blood lead level limits are based on a reference blood lead level based on  
31 the 97.5<sup>th</sup> percentile of the blood lead level distribution among children 1-5 years old in the  
32 United States, which is currently a 5 ug/dL lead level in children<sup>29</sup>; and

33  
34 Whereas, A similar reference blood PFAS level to aim to reduce average PFAS blood levels in  
35 US children to as low a level as possible could be based on the 95th percentile of total serum  
36 concentration of PFAS in U.S. children, which as per the most recent study of National Health  
37 and Nutritional Examination Survey would be 11 ng/dL (0.11 µg/L) with a limit of detection is 0.1  
38 ng/dL (0.001 µg/L) in children ages 3-11 from 2013-14<sup>30</sup>; and

39  
40 Whereas, In 2006, the EPA announced a Product Stewardship agreement with 8 global  
41 manufacturing companies who pledged to reduce PFOA emissions and product content by 95%  
42 in 2010 and work towards its elimination by 2015, and as of February 2017 all participating  
43 companies state they met the PFOA Stewardship Program goals<sup>31,32</sup>; and

44  
45 Whereas, The European Union has phased out contamination from PFAS by severely limiting  
46 the use of PFAS and PFAS derivatives in manufacturing via the REACH Regulation<sup>33</sup>; and

Whereas, Existing AMA policy addresses water contamination by lead (H-135.928, H-60.918), pharmaceuticals (D-135.993), and chlorine (H-135.956), but does not address contamination of drinking water by PFAS chemicals specifically; and

Whereas, Blood screening for water contamination is supported by H-60.924, but no similar policy exists for PFAS; therefore be it

RESOLVED, That our American Medical Association support legislation and regulation seeking to address contamination, exposure, classification, and clean-up of Per- and Polyfluoroalkyl substances. (New HOD Policy)

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

Received: 08/28/19

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## RELEVANT AMA POLICY

### Safe Drinking Water H-135.928

Our AMA supports updates to the U.S. Environmental Protection Agency's Lead and Copper Rule as well as other state and federal laws to eliminate exposure to lead through drinking water by:

- (1) Removing, in a timely manner, lead service lines and other leaded plumbing materials that come into contact with drinking water;
- (2) Requiring public water systems to establish a mechanism for consumers to access information on lead service line locations;
- (3) Informing consumers about the health-risks of partial lead service line replacement;
- (4) Requiring the inclusion of schools, licensed daycare, and health care settings among the sites routinely tested by municipal water quality assurance systems;
- (5) Creating and implementing standardized protocols and regulations pertaining to water quality testing, reporting and remediation to ensure the safety of water in schools and child care centers;
- (6) Improving public access to testing data on water lead levels by requiring testing results from public water systems to be posted on a publicly available website in a reasonable timeframe thereby allowing consumers to take precautions to protect their health;
- (7) Establishing more robust and frequent public education efforts and outreach to consumers that have lead service lines, including vulnerable populations;
- (8) Requiring public water systems to notify public health agencies and health care providers when local water samples test above the action level for lead;
- (9) Seeking to shorten and streamline the compliance deadline requirements in the Safe Drinking Water Act; and
- (10) Actively pursuing changes to the federal lead and copper rules consistent with this policy.

Citation: Res. 409, A-16; Modified: Res. 422, A-18; Reaffirmed: BOT Rep. 29, A-19

### Chemical Analysis Report of Public and Commercial Water D-440.999

Our AMA: (1) requests the appropriate federal agency to require analysis and appropriate labeling of the chemical content, including fluoride, of commercially bottled water, as well as of the water supplies of cities or towns; (2) urges the FDA to require that annual water quality reports from bottled water manufacturers be publicly accessible in a readily available format; and (3) urges the FDA to evaluate bottled water for changes in quality after typical storage conditions.

Citation: (Res. 427, I-98; Reaffirmed: CSAPH Rep. 2, A-08; Modified: CSAPH Rep. 3, A-12)

### Lead Contamination in Municipal Water Systems as Exemplified by Flint, Michigan H-60.918

1. Our AMA will advocate for biologic (including hematological) and neurodevelopmental monitoring at established intervals for children exposed to lead contaminated water with resulting elevated blood lead levels (EBLL) so that they do not suffer delay in diagnosis of adverse consequences of their lead exposure.
2. Our AMA will urge existing federal and state-funded programs to evaluate at-risk children to expand services to provide automatic entry into early-intervention screening programs to assist in the neurodevelopmental monitoring of exposed children with EBLL.
3. Our AMA will advocate for appropriate nutritional support for all people exposed to lead contaminated water with resulting elevated blood lead levels, but especially exposed pregnant women, lactating mothers and exposed children. Support should include Vitamin C, green leafy vegetables and other



calcium resources so that their bodies will not be forced to substitute lead for missing calcium as the children grow.

4. Our AMA promotes screening, diagnosis and acceptable treatment of lead exposure and iron deficiency in all people exposed to lead contaminated water.

Citation: Res. 428, A-16

#### **The Health Risks of Hydraulic Fracturing H-135.931**

1. Our AMA encourages appropriate agencies and organizations to study the potential human and environmental health risks and impacts of hydraulic fracturing.

2. Our AMA: (A) supports the full disclosure of chemicals placed into the natural environment during the petroleum, oil and natural gas exploration and extraction process; and (B) supports the requirement that government agencies record and monitor the chemicals placed into the natural environment for petroleum oil and natural gas extraction and the chemicals found in flowback fluids, to monitor for human exposures in well water and surface water, and to share this information with physicians and the public.

3. Our AMA supports research on the implementation of buffer zones or well set-backs between oil and gas development sites and residences, schools, hospitals, and religious institutions, to determine the distance necessary to ensure public health and safety.

Citation: Res. 405, A-13; Appended: Sub. Res. 508, A-15; Appended: Res. 908, I-17

#### **Contamination of Drinking Water by Pharmaceuticals and Personal Care Products D-135.993**

Our AMA supports the EPA and other federal agencies in engaging relevant stakeholders, which may include, but is not limited to the AMA, pharmaceutical companies, pharmaceutical retailers, state and specialty societies, and public health organizations in the development of guidelines for physicians and the public for the proper disposal of pharmaceuticals and personal care products to prevent contamination of drinking water systems.

Citation: (Sub. Res. 42, I-74; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10

#### **Reducing Lead Poisoning H-60.924**

1. Our AMA: (a) supports regulations and policies designed to protect young children from exposure to lead; (b) urges the Centers for Disease Control and Prevention to give priority to examining the current weight of scientific evidence regarding the range of adverse health effects associated with blood lead concentrations below the current "level of concern" in order to provide appropriate guidance for physicians and public health policy, and encourage the identification of exposure pathways for children who have low blood lead concentrations, as well as effective and innovative strategies to reduce overall childhood lead exposure; (c) encourages physicians and public health departments to screen children based on current recommendations and guidelines and to report all children with elevated blood levels to the appropriate health department in their state or community in order to fully assess the burden of lead exposure in children. In some cases this will be done by the physician, and in other communities by the laboratories; (d) promotes community awareness of the hazard of lead-based paints; and (e) urges paint removal product manufacturers to print precautions about the removal of lead paint to be included with their products where and when sold.

2. Our AMA will call on the United States government to establish national goals to: (a) ensure that no child has a blood lead level  $>5 \mu\text{g/dL}$  ( $>50 \text{ ppb}$ ) by 2021, and (b) eliminate lead exposures to pregnant women and children, so that by 2030, no child would have a blood lead level  $>1 \mu\text{g/dL}$  ( $10 \text{ ppb}$ ).

3. Our AMA will call on the United States government in all its agencies to pursue the following strategies to achieve these goals: (a) adopt health-based standards and action levels for lead that rely on the most up-to-date scientific knowledge to prevent and reduce human exposure to lead, and assure prompt implementation of the strongest available measures to protect pregnant women and children from lead toxicity and neurodevelopmental impairment; (b) identify and remediate current and potential new sources of lead exposure (in dust, air, soil, water and consumer products) to protect children before they are exposed; (c) continue targeted screening of children to identify those who already have elevated blood lead levels for case management, as well as educational and other services; (d) eliminate new sources of lead introduced or released into the environment, which may entail banning or phasing out all remaining uses of lead in products (aviation gas, cosmetics, wheel weights, industrial paints, batteries, lubricants, and other sources), and the export of products containing lead, and setting more protective limits on emissions from battery recyclers and other sources of lead emissions; (e) provide a dedicated funding stream to enhance the resources available to identify and eliminate sources of lead exposure, and

provide educational, social and clinical services to mitigate the harms of lead toxicity, particularly to protect and improve the lives of children in communities that are disproportionately exposed to lead; and (f) establish an independent expert advisory committee to develop a long-term national strategy, including recommendations for funding and implementation, to achieve the national goal of eliminating lead toxicity in pregnant women and children, defined as blood lead levels above 1 µg/dL (10 ppb).

4. Our AMA supports requiring an environmental assessment of dwellings, residential buildings, or child care facilities following the notification that a child occupant or frequent inhabitant has a confirmed elevated blood lead level, to determine the potential source of lead poisoning, including testing the water supply.

Citation: CCB/CLRPD Rep. 3, A-14; Appended: Res. 926, I-16; Appended: Res. 412, A-17

#### **Expansion of Hazardous Waste Landfills Over Aquifers H-135.943**

(1) recognizes that the expansion of hazardous waste landfills or the construction of new hazardous waste landfills over principal aquifers represents a potential health risk for the public water supply and is inconsistent with sound principles of public health policy, and therefore should be opposed;

(2) will advocate for the continued monitoring of groundwater sources, including principal aquifers, that may be contaminated by hazardous waste landfill or other landfill leachate; and

(3) supports efforts to improve hazardous waste treatment, recycling, and disposal methods in order to reduce the public health burden.

Citation: CSAPH Rep. 4, A-07; Reaffirmed: CSAPH Rep. 01, A-17

#### **Human and Environmental Health Impacts of Chlorinated Chemicals H-135.956**

(1) Our AMA encourages the Environmental Protection Agency to base its evaluations of the potential public health and environmental risks posed by exposure to an individual chlorinated organic compound, other industrial compound, or manufacturing process on reliable data specific to that compound or process;

(2) encourages the chemical industry to increase knowledge of the environmental behavior, bioaccumulation potential, and toxicology of their products and by-products; and

(3) supports the implementation of risk reduction practices by the chemical and manufacturing industries.

Citation: Sub. Res. 503, A-94; Reaffirmation I-98; Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmation I-16

#### **EPA and Green House Gas Regulation H-135.934**

1. Our AMA supports the Environmental Protection Agency's authority to promulgate rules to regulate and control green house gas emissions in the United States.

2. Our AMA: (a) strongly supports evidence-based environmental statutes and regulations intended to regulate air and water pollution and to reduce greenhouse gas emissions; and (b) will advocate that environmental health regulations should only be modified or rescinded with scientific justification.

Citation: Res. 925, I-10; Reaffirmed in lieu of Res. 526, A-12; Reaffirmed: Res. 421, A-14; Appended: Res. 523, A-17

#### **Guidance for Worldwide Conservation of Potable Water H-135.947**

Our AMA favors scientific and cultural development of a plan for worldwide potable water conservation, especially in countries affected by natural disasters or other events that disrupt the potable water supply.

Citation: (Res. 406, A-04; Modified in lieu of Res. 906, I-11)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 902  
(I-19)

Introduced by: Medical Student Section

Subject: Amending H-490.913, "Smoke-Free Environments and Workplaces," and  
H-490.907, "Tobacco Smoke Exposure of Children in Multi-Unit Housing," to  
Include E-Cigarettes

Referred to: Reference Committee K

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1 Whereas, The use of e-cigarettes, otherwise known as vaping, has become increasingly popular  
2 for nicotine usage among youth, new smokers, and those seeking smoking cessation options<sup>1,2</sup>;  
3 and  
4

5 Whereas, Among middle school students, current e-cigarette use increased by 48% during  
6 2017-2018<sup>3</sup>; and  
7

8 Whereas, Among high school students, current e-cigarette use increased from 1.5% in 2011 to  
9 20.8% in 2018<sup>3</sup>; and  
10

11 Whereas, In 2018, more than 3.6 million U.S. youth, including 1 in 5 high school students and 1  
12 in 20 middle school students currently used e-cigarettes, resulting in a different population  
13 exposed to the toxic effects of secondhand smoke due to e-cigarette use than due to cigarette  
14 use<sup>3</sup>; and  
15

16 Whereas, College students who use electronic nicotine delivery systems (ENDS) are more than  
17 twice as likely to initiate cigarette use<sup>4</sup>; and  
18

19 Whereas, During an assessment of indoor air quality at an e-cigarette (vaping) convention, it  
20 was found that e-cigarette use was a major source of particulate matter, air nicotine, and real-  
21 time total volatile organic compounds, impairing indoor air quality<sup>5</sup>; and  
22

23 Whereas, E-cigarette use indoors increased particulate matter concentrations 160-fold at 0.5m  
24 and 103-fold at 1m, showing that particulate matter increases as proximity to the e-cigarette  
25 increases<sup>6</sup>; and  
26

27 Whereas, When characterizing nicotine persistence on surfaces over a 72-hr period, residual  
28 nicotine concentrations persisted on both terry cloth and glass surfaces for 72 hours, and was  
29 found to persist long enough to pose a potential third hand nicotine exposure risk<sup>7</sup>; and  
30

31 Whereas, It has been shown that vaping worsens indoor air quality by increasing the  
32 concentration of nicotine, particulate matter, polycyclic aromatic hydrocarbons, and aluminum--  
33 all substances associated with increased risk for lung and cardiovascular disease and cancer<sup>8</sup>;  
34 and

Whereas, Oxidants and reactive oxygen species reactivity in e-cigarette aerosols was similar to that in traditional cigarette smoke, with copper levels being found at much higher levels in e-cigarettes<sup>9</sup>; and

Whereas, A systematic review found that e-cigarette vapor may lead to adverse health effects, such as an increased risk of cardiovascular and respiratory diseases and certain cancers<sup>10,11</sup>; and

Whereas, These adverse health effects may extend to non-users due to secondhand vapor exposure, especially those who are pregnant or children<sup>11,12</sup>; and

Whereas, Nicotine exposure during adolescence can harm the developing brain, impacting learning, memory, and attention as well as increasing risk for future addiction to other drugs<sup>2</sup>; and

Whereas, Smoke-free policies were designed to protect non-smokers from toxic irritants, incentivize smoking cessation, and denormalize smoking<sup>13</sup>; and

Whereas, The use of e-cigarettes where smoke-free policies are implemented increases exposure risk to non-user bystanders, reduces cessation initiatives, and may promote the renormalization of smoking<sup>13</sup>; and

Whereas, Users who were not able to vape indoors would use less frequently and were less dependent on e-cigarettes<sup>14</sup>; and

Whereas, 26.1% (n=1034) of users reported not being able to vape in places where smoking is typically banned, while 73.9% (n=2926) reported being able to vape in places where smoking is typically banned<sup>14</sup>; and

Whereas, 15 states and 814 municipalities have currently prohibited the use of e-cigarettes in the same places where cigarette smoking is prohibited, which means that approximately 70% of states remain unprotected<sup>15,16</sup>; and

Whereas, Our AMA recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and is actively working to counteract the marketing and use of addictive e-cigarette and vaping devices (AMA policy H-495.986); therefore be it

RESOLVED, That our American Medical Association amend policy H-490.913, "Smoke-Free Environments and Workplaces," by addition and deletion to read as follows:

**Smoke-Free and Vape-Free Environments and Workplaces, H-490.913**

On the issue of the health effects of environmental tobacco smoke (ETS), ~~and~~ passive smoke, and vape exposure in the workplace and other public facilities, our AMA: (1)(a) supports classification of ETS as a known human carcinogen; (b) concludes that passive smoke exposure is associated with increased risk of sudden infant death syndrome and of cardiovascular disease; (c) encourages physicians and medical societies to take a leadership role in defending the health of the public from ETS risks and from political assaults by the tobacco industry; and (d) encourages the concept of establishing smoke-free and vape-free campuses for business, labor, education, and government; (2) (a) honors companies and governmental workplaces that go smoke-free and vape-free; (b) will petition the Occupational Safety and Health Administration (OSHA) to adopt regulations prohibiting smoking and vaping in the

workplace, and will use active political means to encourage the Secretary of Labor to swiftly promulgate an OSHA standard to protect American workers from the toxic effects of ETS in the workplace, preferably by banning smoking and vaping in the workplace; (c) encourages state medical societies (in collaboration with other anti-tobacco organizations) to support the introduction of local and state legislation that prohibits smoking and vaping around the public entrances to buildings and in all indoor public places, restaurants, bars, and workplaces; and (d) will update draft model state legislation to prohibit smoking and vaping in public places and businesses, which would include language that would prohibit preemption of stronger local laws. (3) (a) encourages state medical societies to: (i) support legislation for states and counties mandating smoke-free and vape-free schools and eliminating smoking and vaping in public places and businesses and on any public transportation; (ii) enlist the aid of county medical societies in local anti-smoking and anti-vaping campaigns; and (iii) through an advisory to state, county, and local medical societies, urge county medical societies to join or to increase their commitment to local and state anti-smoking and anti-vaping coalitions and to reach out to local chapters of national voluntary health agencies to participate in the promotion of anti-smoking and anti-vaping control measures; (b) urges all restaurants, particularly fast food restaurants, and convenience stores to immediately create a smoke-free and vape-free environment; (c) strongly encourages the owners of family-oriented theme parks to make their parks smoke-free and vape-free for the greater enjoyment of all guests and to further promote their commitment to a happy, healthy life style for children; (d) encourages state or local legislation or regulations that prohibit smoking and vaping in stadia and encourages other ball clubs to follow the example of banning smoking in the interest of the health and comfort of baseball fans as implemented by the owner and management of the Oakland Athletics and others; (e) urges eliminating cigarette, pipe, cigar, and e-cigarette smoking in any indoor area where children live or play, or where another person's health could be adversely affected through passive smoking inhalation; (f) urges state and county medical societies and local health professionals to be especially prepared to alert communities to the possible role of the tobacco industry whenever a petition to suspend a nonsmoking or non-vaping ordinance is introduced and to become directly involved in community tobacco control activities; and (g) will report annually to its membership about significant anti-smoking and anti-vaping efforts in the prohibition of smoking and vaping in open and closed stadia; (4) calls on corporate headquarters of fast-food franchisers to require that one of the standards of operation of such franchises be a no smoking and no vaping policy for such restaurants, and endorses the passage of laws, ordinances and regulations that prohibit smoking and vaping in fast-food restaurants and other entertainment and food outlets that target children in their marketing efforts; (5) advocates that all American hospitals ban tobacco and supports working toward legislation and policies to promote a ban on smoking, vaping, and use of tobacco products in, or on the campuses of, hospitals, health care institutions, retail health clinics, and educational institutions, including medical schools; (6) will work with the Department of Defense to explore ways to encourage a smoke-free and vape-free environment in the military through the use of mechanisms such as health education, smoking and vaping cessation programs, and the elimination of discounted prices for tobacco products in military resale facilities; and (7) encourages and supports local and state medical societies and tobacco control coalitions to work with (a) Native American casino and tribal leadership to voluntarily prohibit smoking and vaping in their casinos; and (b) legislators and the gaming industry to support the prohibition of smoking and vaping in all casinos and gaming venues (Modify Current HOD Policy); and be it further

1 RESOLVED, That our AMA amend Policy H-490.907, "Tobacco Smoke Exposure of  
2 Children in Multi-Unit Housing," to include e-cigarettes and vaping by addition to read  
3 as follows:  
4

5 **Tobacco Smoke and Vaping Exposure of Children in Multi-Unit Housing,**  
6 **H-490.907**

7 Our AMA: (1) encourages federal, state and local housing authorities and  
8 governments to adopt policies that protect children and non-smoking or non-vaping  
9 adults from tobacco smoke and vaping exposure by prohibiting smoking and vaping in  
10 multi-unit housing; and (2) encourages state and local medical societies, chapters,  
11 and other health organizations to support and advocate for changes in existing state  
12 and local laws and policies that protect children and non-smoking or non-vaping  
13 adults from tobacco smoke and vaping exposure by prohibiting smoking and vaping in  
14 multi-unit housing. (Modify Current HOD Policy)

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

Received: 08/28/19

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## RELEVANT AMA POLICY

### Smoke-Free Environments and Workplaces H-490.913

On the issue of the health effects of environmental tobacco smoke (ETS) and passive smoke exposure in the workplace and other public facilities, our AMA:

- (1) (a) supports classification of ETS as a known human carcinogen; (b) concludes that passive smoke exposure is associated with increased risk of sudden infant death syndrome and of cardiovascular disease; (c) encourages physicians and medical societies to take a leadership role in defending the health of the public from ETS risks and from political assaults by the tobacco industry; and (d) encourages the concept of establishing smoke-free campuses for business, labor, education, and government;
- (2) (a) honors companies and governmental workplaces that go smoke-free; (b) will petition the Occupational Safety and Health Administration (OSHA) to adopt regulations prohibiting smoking in the workplace, and will use active political means to encourage the Secretary of Labor to swiftly promulgate an OSHA standard to protect American workers from the toxic effects of ETS in the workplace, preferably by banning smoking in the workplace; (c) encourages state medical societies (in collaboration with other anti-tobacco organizations) to support the introduction of local and state legislation that prohibits smoking around the public entrances to buildings and in all indoor public places, restaurants, bars, and workplaces; and (d) will update draft model state legislation to prohibit smoking in public places and businesses, which would include language that would prohibit preemption of stronger local laws.
- (3) (a) encourages state medical societies to: (i) support legislation for states and counties mandating smoke-free schools and eliminating smoking in public places and businesses and on any public transportation; (ii) enlist the aid of county medical societies in local anti-smoking campaigns; and (iii) through an advisory to state, county, and local medical societies, urge county medical societies to join or to increase their commitment to local and state anti-smoking coalitions and to reach out to local chapters of national voluntary health agencies to participate in the promotion of anti-smoking control measures; (b) urges all restaurants, particularly fast food restaurants, and convenience stores to immediately create a smoke-free environment; (c) strongly encourages the owners of family-oriented theme parks to make their parks smoke-free for the greater enjoyment of all guests and to further promote their commitment to a happy, healthy life style for children; (d) encourages state or local legislation or regulations that prohibit smoking in stadia and encourages other ball clubs to follow the example of banning smoking in the interest of the health and comfort of baseball fans as implemented by the owner and management of the Oakland Athletics and others; (e) urges eliminating cigarette, pipe, and cigar smoking in any indoor area where children live or play, or where another person's health could be adversely affected through passive smoking; (f) urges state and county medical societies and local health professionals to be especially prepared to alert communities to the possible role of the tobacco industry whenever a petition to suspend a nonsmoking ordinance is introduced and to become directly involved in community tobacco control activities; and (g) will report annually to its membership about significant anti-smoking efforts in the prohibition of smoking in open and closed stadia;
- (4) calls on corporate headquarters of fast-food franchisers to require that one of the standards of operation of such franchises be a no smoking policy for such restaurants, and endorses the passage of laws, ordinances and regulations that prohibit smoking in fast-food restaurants and other entertainment and food outlets that target children in their marketing efforts;
- (5) advocates that all American hospitals ban tobacco and supports working toward legislation and policies to promote a ban on smoking and use of tobacco products in, or on the campuses of, hospitals, health care institutions, retail health clinics, and educational institutions, including medical schools;
- (6) will work with the Department of Defense to explore ways to encourage a smoke-free environment in the military through the use of mechanisms such as health education, smoking cessation programs, and the elimination of discounted prices for tobacco products in military resale facilities; and
- (7) encourages and supports local and state medical societies and tobacco control coalitions to work with (a) Native American casino and tribal leadership to voluntarily prohibit smoking in their casinos; and (b) legislators and the gaming industry to support the prohibition of smoking in all casinos and gaming venues.

Citation: (CSA Rep. 3, A-04; Appended: Sub. Res. 426, A-04; Modified: CSAPH Rep. 1, I-07; Reaffirmation I-14; Reaffirmation I-15)

### **Sales and Distribution of Tobacco Products and Electronic Nicotine Delivery Systems (ENDS) and E-cigarettes H-495.986**

Our AMA:

- (1) recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and will actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices, including but not limited to bans and strict restrictions on marketing to minors under the age of 21;
- (2) encourages the passage of laws, ordinances and regulations that would set the minimum age for purchasing tobacco products, including electronic nicotine delivery systems (ENDS) and e-cigarettes, at 21 years, and urges strict enforcement of laws prohibiting the sale of tobacco products to minors;
- (3) supports the development of model legislation regarding enforcement of laws restricting children's access to tobacco, including but not limited to attention to the following issues: (a) provision for licensure to sell tobacco and for the revocation thereof; (b) appropriate civil or criminal penalties (e.g., fines, prison terms, license revocation) to deter violation of laws restricting children's access to and possession of tobacco; (c) requirements for merchants to post notices warning minors against attempting to purchase tobacco and to obtain proof of age for would-be purchasers; (d) measures to facilitate enforcement; (e) banning out-of-package cigarette sales ("loosies"); and (f) requiring tobacco purchasers and vendors to be of legal smoking age;
- (4) requests that states adequately fund the enforcement of the laws related to tobacco sales to minors;
- (5) opposes the use of vending machines to distribute tobacco products and supports ordinances and legislation to ban the use of vending machines for distribution of tobacco products;
- (6) seeks a ban on the production, distribution, and sale of candy products that depict or resemble tobacco products;
- (7) opposes the distribution of free tobacco products by any means and supports the enactment of legislation prohibiting the disbursement of samples of tobacco and tobacco products by mail;
- (8) (a) publicly commends (and so urges local medical societies) pharmacies and pharmacy owners who have chosen not to sell tobacco products, and asks its members to encourage patients to seek out and patronize pharmacies that do not sell tobacco products; (b) encourages other pharmacists and pharmacy owners individually and through their professional associations to remove such products from their stores; (c) urges the American Pharmacists Association, the National Association of Retail Druggists, and other pharmaceutical associations to adopt a position calling for their members to remove tobacco products from their stores; and (d) encourages state medical associations to develop lists of pharmacies that have voluntarily banned the sale of tobacco for distribution to their members; and
- (9) opposes the sale of tobacco at any facility where health services are provided; and
- (10) supports that the sale of tobacco products be restricted to tobacco specialty stores. Citation: CSA Rep. 3, A-04; Appended: Res. 413, A-04; Reaffirmation A-07; Amended: Res. 817, I-07; Reaffirmation A-08; Reaffirmation I-08; Reaffirmation A-09; Reaffirmation I-13; Reaffirmation A-14; Reaffirmation I-14; Reaffirmation A-15; Modified in lieu of Res. 421, A-15; Modified in lieu of Res. 424, A-15; Reaffirmation I-16; Appended: Res. 926, I-18

### **Electronic Cigarettes, Vaping, and Health H-495.972**

1. Our AMA urges physicians to: (a) educate themselves about electronic nicotine delivery systems (ENDS), including e-cigarettes, be prepared to counsel patients about the use of these products and the potential for nicotine addiction and the potential hazards of dual use with conventional cigarettes, and be sensitive to the possibility that when patients ask about e-cigarettes, they may be asking for help to quit smoking; (b) consider expanding clinical interviews to inquire about "vaping" or the use of e-cigarettes; (c) promote the use of FDA-approved smoking cessation tools and resources for their patients and caregivers; and (d) advise patients who use e-cigarettes to take measures to assure the safety of children in the home who could be exposed to risks of nicotine overdose via ingestion of replacement e-cigarette liquid that is capped or stored improperly.
2. Our AMA: (a) encourages further clinical and epidemiological research on e-cigarettes; (b) supports education of the public on the health effects, including toxins and carcinogens of electronic nicotine delivery systems (ENDS) including e-cigarettes; and (c) recognizes that the use of products containing nicotine in any form among youth, including e-cigarettes, is unsafe and can cause addiction.
3. Our AMA supports legislation and associated initiatives and will work in coordination with the Surgeon General to prevent e-cigarettes from reaching youth and young adults through various means, including, but not limited to, CDC research, education and a campaign for preventing and reducing use by youth, young adults and others of e-cigarettes, and combustible and emerging tobacco products.



Citation: CSAPH Rep. 2, I-14; Modified in lieu of Res. 412, A-15; Modified in lieu of Res. 419, A-15; Reaffirmed: Res. 421, A-15; Modified: CSAPH Rep. 05, A-18; Reaffirmed: CSAPH Rep. 03, A-19; Appended: Res. 428, A-19;

### **FDA to Extend Regulatory Jurisdiction Over All Non-Pharmaceutical Nicotine and Tobacco Products H-495.973**

Our AMA: (1) supports the U.S. Food and Drug Administration's (FDA) proposed rule that would implement its deeming authority allowing the agency to extend FDA regulation of tobacco products to pipes, cigars, hookahs, e-cigarettes and all other non-pharmaceutical tobacco/nicotine products not currently covered by the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act; (2) supports legislation and/or regulation of electronic cigarettes and all other non-pharmaceutical tobacco/nicotine products that: (a) establishes a minimum legal purchasing age of 21; (b) prohibits use in all places that tobacco cigarette use is prohibited, including in hospitals and other places in which health care is delivered; (c) applies the same marketing and sales restrictions that are applied to tobacco cigarettes, including prohibitions on television advertising, product placement in television and films, and the use of celebrity spokespeople; (d) prohibits product claims of reduced risk or effectiveness as tobacco cessation tools, until such time that credible evidence is available, evaluated, and supported by the FDA; (e) requires the use of secure, child- and tamper-proof packaging and design, and safety labeling on containers of replacement fluids (e-liquids) used in e-cigarettes; (f) establishes manufacturing and product (including e-liquids) standards for identity, strength, purity, packaging, and labeling with instructions and contraindications for use; (g) requires transparency and disclosure concerning product design, contents, and emissions; and (h) prohibits the use of characterizing flavors that may enhance the appeal of such products to youth; and (3) urges federal officials, including but not limited to the U.S. Food and Drug Administration to: (a) prohibit the sale of any e-cigarette cartridges and e-liquid refills that do not include a complete list of ingredients on its packaging, in the order of prevalence (similar to food labeling); and (b) require that an accurate nicotine content of e-cigarettes, e-cigarette cartridges, and e-liquid refills be prominently displayed on the product alongside a warning of the addictive quality of nicotine.

Citation: Res. 206, I-13; Modified in lieu of Res. 511, A-14; Modified in lieu of Res. 518, A-14; Modified in lieu of Res. 519, A-14; Modified in lieu of Res. 521, A-14; Modified: CSAPH Rep. 2, I-14; Reaffirmation A-15; Reaffirmed in lieu of Res. 412, A-15; Reaffirmed in lieu of Res. 419, A-15; Reaffirmed: Res. 421, A-15; Reaffirmation A-16; Appended: Res. 429, A-18; Modified: CSAPH Rep. 05, A-18

### **FDA Regulation of Tobacco Products H-495.988**

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

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

physician and public health organizations in submitting comments on FDA proposed rule to regulate all tobacco products.

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

Citation: CSA Rep. 3, A-04; Reaffirmed: BOT Rep. 8, A-08; Appended: Res. 234, A-12; Reaffirmation A-13; Modified: Res. 402, A-13; Modified: Speakers Rep., A-14; Appended: Res. 420, A-14; Reaffirmation A-15; Modified: CSAPH Rep. 05, A-18; Reaffirmed in lieu of: Res. 412, A-19; Modified: CSAPH Rep. 03, A-19

#### **Secondhand Smoke H-490.910**

1. Our AMA urges the President of the United States to issue an Executive Order making all federal workplaces, including buildings and campuses, entirely smoke free and urges its federation members to do the same.

2. Our AMA supports legislation that prohibits smoking while operating or riding in a vehicle that contains children.

Citation: (Res. 417, A-09; Appended: Res. 202, A-14)

#### **Tobacco Smoke Exposure of Children in Multi-Unit Housing H-490.907**

Our AMA: (1) encourages federal, state and local housing authorities and governments to adopt policies that protect children and non-smoking adults from tobacco smoke exposure by prohibiting smoking in multi-unit housing; and (2) encourages state and local medical societies, chapters, and other health organizations to support and advocate for changes in existing state and local laws and policies that protect children and non-smoking adults from tobacco smoke exposure by prohibiting smoking in multi-unit housing.

#### **Tobacco-Free School Environment H-490.908**

Our AMA: (1) supports and advocates for a tobacco-free school environment (as defined by the CDC) as the cornerstone of a comprehensive policy intended to prevent and reduce tobacco use and addiction in young people; (2) supports the adoption of tobacco-free school laws or policies that incorporate the guidelines developed by the Centers for Disease Control and Prevention for school-based health programs to prevent tobacco use and addiction; (3) will provide a link on its website of existing resources to assist those at the state and local levels who are interested in pursuing tobacco free school environments; and (4) urges its Federation members to collaborate with students, parents, school officials and members of the community to establish tobacco free schools.

Citation: (Res. 418, A-10)

#### **Oppose Efforts to Stop, Weaken or Delay FDA's Authority to Regulate All Tobacco Products D-495.993**

1. Our AMA encourages Congress to oppose any legislation that would stop, weaken, or delay FDA's authority to fully regulate all tobacco products.

2. Our AMA will write a letter to the Administration expressing our strong opposition to the decision to strike from the Food and Drug Administration's deeming rule on tobacco products, the restriction of flavored electronic nicotine delivery systems.

Citation: Res. 425, A-16

#### **Banning Smoking in All Workplaces D-490.979**

Our AMA will (1) actively support national, state, and local legislation and actively pursue regulations banning smoking in all workplaces; and (2) work to ensure that federal legislation banning smoking in all workplaces does not prohibit or weaken more strict state or local regulations.

Citation: Res. 903, I-05; Modified: Res. 401, A-06; Reaffirmed: CSAPH 01, A-16

## AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 903  
(I-19)

Introduced by: Medical Student Section

Subject: Encouraging the Development of Multi-Language, Culturally Informed Mobile Health Applications

Referred to: Reference Committee K

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Whereas, There is a scarcity of mobile health applications addressing the needs of patients receiving costly care, in poor health, or of low English literacy<sup>1</sup>; and

Whereas, Longstanding disparities in health burden minority and low-income communities and persist at all levels of health care, from access to health insurance, preventive services, and high-quality care to condition-specific burden, morbidity, and mortality<sup>2,3</sup>; and

Whereas, Concern has been raised that current mobile health technologies may exacerbate existing disparities by precluding individuals of low socioeconomic status from potential financial rewards or health benefits<sup>3,4</sup>; and

Whereas, Existing national policy fails to address barriers to equal access to mobile health technologies for vulnerable, culturally diverse, and low-income communities<sup>2,5</sup>; and

Whereas, The National Standards for Culturally and Linguistically Appropriate Services in Health and Health Care, published by the U.S. Department of Health and Human Services, do not contain provisions relating to mobile health application development<sup>6</sup>; and

Whereas, English language fluency varies widely among cultural subgroups, from 31% of Hispanics to 51% of Vietnamese Americans who report non-fluency<sup>2</sup>; and

Whereas, A study of Hispanic migrant farm workers, a patient population with high burden of chronic disease and limited access to healthcare, found 81% of this population has access to mobile devices and the majority are receptive to using mobile health platforms for facilitation of medication adherence and management of chronic conditions<sup>7</sup>; and

Whereas, A 2018 study noted that a uniquely designed mobile health app could facilitate smoking cessation in LGBTQ+ young adults, who engage in tobacco use at much higher rates than the general population<sup>8</sup>; and

Whereas, The pervasiveness of smartphone use may serve as a means to deliver health-related interventions to racial and ethnic minority groups<sup>9</sup>; and

Whereas, The timely and convenient interventions offered by mobile devices, such as personalized medication reminders, have the potential to enhance the health of minority and low-income individuals, to reduce the costs of their medical care, and to close health gaps between populations<sup>7,10</sup>; and

Whereas, Our AMA has resolved to “identify and incorporate strategies specific to the elimination of minority health disparities in its ongoing advocacy and public health efforts” (D-350.996); therefore be it

RESOLVED, That American Medical Association amend policy D-480.972 by addition to read as follows:

Guidelines for Mobile Medical Applications and Devices, D-480.972

1. Our AMA will monitor market developments in mobile health (mHealth), including the development and uptake of mHealth apps, in order to identify developing consensus that provides opportunities for AMA involvement.
2. Our AMA will continue to engage with stakeholders to identify relevant guiding principles to promote a vibrant, useful and trustworthy mHealth market.
3. Our AMA will make an effort to educate physicians on mHealth apps that can be used to facilitate patient communication, advice, and clinical decision support, as well as resources that can assist physicians in becoming familiar with mHealth apps that are clinically useful and evidence-based.
4. Our AMA will develop and publicly disseminate a list of best practices guiding the development and use of mobile medical applications.
5. Our AMA encourages further research integrating mobile devices into clinical care, particularly to address challenges of reducing work burden while maintaining clinical autonomy for residents and fellows.
6. Our AMA will collaborate with the Liaison Committee on Medical Education and Accreditation Council for Graduate Medical Education to develop germane policies, especially with consideration of potential financial burden and personal privacy of trainees, to ensure more uniform regulation for use of mobile devices in medical education and clinical training.
7. Our AMA encourages medical schools and residency programs to educate all trainees on proper hygiene and professional guidelines for using personal mobile devices in clinical environments.
8. Our AMA encourages the development of mobile health applications that employ linguistically appropriate and culturally informed content catered to underserved and low-income populations. (Modify Current HOD Policy)

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

Received: 08/28/19

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## **RELEVANT AMA POLICY:**

### **Integration of Mobile Health Applications and Devices into Practice D-480.967**

Our AMA will: (1) assess the potential liability risks to physicians for using, recommending, or prescribing mHealth apps, including risk under federal and state medical liability, privacy, and security laws; and (2) assess the feasibility of state and federal legislation, as well as other innovative alternatives, in an effort to mitigate the physician's potential risk of liability from the use or recommendation of mHealth apps.

Citation: CMS Rep. 06, I-16

### **Guidelines for Mobile Medical Applications and Devices D-480.972**

1. Our AMA will monitor market developments in mobile health (mHealth), including the development and uptake of mHealth apps, in order to identify developing consensus that provides opportunities for AMA involvement.
2. Our AMA will continue to engage with stakeholders to identify relevant guiding principles to promote a vibrant, useful and trustworthy mHealth market.
3. Our AMA will make an effort to educate physicians on mHealth apps that can be used to facilitate patient communication, advice, and clinical decision support, as well as resources that can assist physicians in becoming familiar with mHealth apps that are clinically useful and evidence-based.
4. Our AMA will develop and publicly disseminate a list of best practices guiding the development and use of mobile medical applications.
5. Our AMA encourages further research integrating mobile devices into clinical care, particularly to address challenges of reducing work burden while maintaining clinical autonomy for residents and fellows.
6. Our AMA will collaborate with the Liaison Committee on Medical Education and Accreditation Council for Graduate Medical Education to develop germane policies, especially with consideration of potential financial burden and personal privacy of trainees, to ensure more uniform regulation for use of mobile devices in medical education and clinical training.
7. Our AMA encourages medical schools and residency programs to educate all trainees on proper hygiene and professional guidelines for using personal mobile devices in clinical environments.

Citation: CSAPH Rep. 5, A-14; Appended: Res. 201, A-15; Appended: Res. 305, I-16

### **Integration of Mobile Health Applications and Devices into Practice H-480.943**

1. Our AMA supports the establishment of coverage, payment and financial incentive mechanisms to support the use of mobile health applications (mHealth apps) and associated devices, trackers and sensors by patients, physicians and other providers that: (a) support the establishment or continuation of a valid patient-physician relationship; (b) have a high-quality clinical evidence base to support their use in order to ensure mHealth app safety and effectiveness; (c) follow evidence-based practice guidelines, especially those developed and produced by national medical specialty societies and based on systematic reviews, to ensure patient safety, quality of care and positive health outcomes; (d) support care delivery that is patient-centered, promotes care coordination and facilitates team-based communication; (e) support data portability and interoperability in order to promote care coordination through medical home and accountable care models; (f) abide by state licensure laws and state medical practice laws and requirements in the state in which the patient receives services facilitated by the app; (g) require that physicians and other health practitioners delivering services through the

app be licensed in the state where the patient receives services, or be providing these services as otherwise authorized by that state's medical board; and (h) ensure that the delivery of any services via the app be consistent with state scope of practice laws.

2. Our AMA supports that mHealth apps and associated devices, trackers and sensors must abide by applicable laws addressing the privacy and security of patients' medical information.

3. Our AMA encourages the mobile app industry and other relevant stakeholders to conduct industry-wide outreach and provide necessary educational materials to patients to promote increased awareness of the varying levels of privacy and security of their information and data afforded by mHealth apps, and how their information and data can potentially be collected and used.

4. Our AMA encourages the mHealth app community to work with the AMA, national medical specialty societies, and other interested physician groups to develop app transparency principles, including the provision of a standard privacy notice to patients if apps collect, store and/or transmit protected health information.

5. Our AMA encourages physicians to consult with qualified legal counsel if unsure of whether an mHealth app meets Health Insurance Portability and Accountability Act standards and also inquire about any applicable state privacy and security laws.

6. Our AMA encourages physicians to alert patients to the potential privacy and security risks of any mHealth apps that he or she prescribes or recommends, and document the patient's understanding of such risks

7. Our AMA supports further development of research and evidence regarding the impact that mHealth apps have on quality, costs, patient safety and patient privacy.

8. Our AMA encourages national medical specialty societies to develop guidelines for the integration of mHealth apps and associated devices into care delivery.

Citation: CMS Rep. 06, I-16; Reaffirmation: A-17

## AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 904  
(I-19)

Introduced by: Medical Student Section

Subject: Amendment to AMA Policy H-150.949, "Healthy Food Options in Hospitals"

Referred to: Reference Committee K

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Whereas, Medical care facilities include hospitals, skilled nursing facilities, intermediate care facilities, and correctional treatment facilities such as prisons<sup>1,2</sup>; and

Whereas, Current AMA policy H-150.949 encourages healthy, plant-based options to be provided within hospitals, but does not explicitly encourage the same of other medical care facilities; and

Whereas, There is a lack of consistency in food safety and option regulations among prisons at the local and state level<sup>3-6</sup>; and

Whereas, Centers for Medicare & Medicaid Services regulations require nursing facilities to provide a "nourishing, palatable, well-balanced diet that meets ... daily nutritional and special dietary needs", but does not explicitly address plant-based diets<sup>7</sup>; and

Whereas, A study found 65% of nursing home residents expressed complaints about their food service and the presence of complaints was related to poor food intake<sup>8</sup>; and

Whereas, Plant-based diets have been shown to improve health in all people, not just hospitalized patients<sup>9-14</sup>; and

Whereas, Plant-based options also have the potential to be cheaper than alternatives depending on the decisions made by individual facilities regarding costs for purchase, storage and preparation<sup>17-19</sup>; therefore be it

RESOLVED, That our American Medical Association encourage the availability of healthy, plant-based options at medical care facilities by amending AMA Policy H-150.949, "Healthy Food Options in Hospitals," by addition and deletion to read as follows:

**Healthy Food Options in ~~Hospitals~~ Medical Care Facilities, H-150.949**

1. Our AMA encourages healthy food options be available, at reasonable prices and easily accessible, on ~~hospital~~ the premises of Medical Care Facilities.

2. Our AMA hereby calls on ~~US hospitals~~ all Medical Care Facilities and Correctional Facilities to improve the health of patients, staff, and visitors by: (a) providing a variety of healthy food, including plant-based meals, and meals that are low in fat, sodium, and added sugars; (b) eliminating processed meats from menus; and (c) providing and promoting healthy beverages.

3. Our AMA hereby calls for ~~hospital~~ Medical Care Facility cafeterias and inpatient meal menus to publish nutrition information. (Modify Current HOD Policy)

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

Received: 08/28/19

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## RELEVANT AMA POLICY:

### Dietary Intake of Incarcerated Populations D-430.995

Our AMA: 1) urges the National Commission on Correctional Health Care, the American Correctional Association, and individual states to mandate adherence to the current Dietary Reference Intakes and Dietary Guidelines for Americans (with adjustments, as needed, for special populations) as a criterion for accreditation and/or standards compliance, until national dietary guidelines specific for adolescent and adult incarcerated populations becomes available; and 2) urges the Food and Nutrition Board of the Institute of Medicine to examine the nutrient status and dietary requirements of incarcerated populations and issue guidelines on menu planning for adolescent and adult incarcerated populations.

Citation: (CSAPH Rep. 4, A-11)

### Nutrition Labeling and Nutritionally Improved Menu Offerings in Fast-Food and Other Chain Restaurants H-150.945

Our AMA:

1. supports federal, state, and local policies to require fast-food and other chain restaurants with 10 or more units (smaller, neighborhood restaurants could be exempt) to provide consumers with nutrition information on menus and menu boards;
2. recommends that nutrition information in fast-food and other chain restaurants include calorie, fat, saturated fat and trans fat, and sodium labeling on printed menus, and, at a minimum,



calories on menu boards, since they have limited space, and that all nutrition information be conspicuous and easily legible;

3. urges federal, state, and local health agencies, health organizations, and physicians and other health professionals to educate people how to use the nutrition information provided in restaurants to make healthier food choices for themselves and their families; and

4. urges restaurants to improve the nutritional quality of their menu offerings--for example, by reducing caloric content; offering smaller portions; offering more fruits, vegetables, and whole-grain items; using less sodium; using cooking fats lower in saturated and trans fats; and using less added sugars/sweeteners.

Citation: Res. 419, A-07; Reaffirmed in lieu of Res. 413, A-09, Res. 416, A-09 and Res. 418, A-09; Reaffirmed: CSAPH Rep. 01, A-19

#### **H-150.944 Increasing Healthy Food Options in School Lunches for Elementary and Middle School Students**

Our AMA supports efforts to: (1) reduce health disparities by basing food assistance programs on the health needs of their constituents; (2) provide vegetables, fruits, legumes, grains, vegetarian foods, and healthful dairy and nondairy beverages in school lunches and food assistance programs; and (3) ensure that federal subsidies encourage the consumption of foods and beverages low in fat, added sugars, and cholesterol.

Citation: Res. 413, A-07; Reaffirmation A-12; Reaffirmation A-13; Modified: CSAPH Rep. 03, A-17

#### **H-150.949 Health Food Options in Hospitals**

1. Our AMA encourages healthy food options be available, at reasonable prices and easily accessible, on hospital premises.

2. Our AMA hereby calls on US hospitals to improve the health of patients, staff, and visitors by: (a) providing a variety of healthy food, including plant-based meals, and meals that are low in fat, sodium, and added sugars; (b) eliminating processed meats from menus; and (c) providing and promoting healthy beverages.

3. Our AMA hereby calls for hospital cafeterias and inpatient meal menus to publish nutrition information.

Citation: Res. 410, A-04; Reaffirmed: CSAPH Rep. 1, A-14; Appended: Res. 406, A-17; Modified: Res. 425, A-18

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 905  
(I-19)

Introduced by: Medical Student Section

Subject: Sunscreen Dispensers in Public Spaces as a Public Health Measure

Referred to: Reference Committee K

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Whereas, One in five Americans will develop skin cancer in their lifetime, and five million Americans will be treated for skin cancer this year alone<sup>1</sup>; and

Whereas, The annual cost of treating skin cancers in the United States is estimated to be \$8.1 billion<sup>1,2</sup>; and

Whereas, Most skin cancers are a direct result of exposure to the UV rays in sunlight<sup>3</sup>; and

Whereas, One bad sunburn can demonstrably increase the chances of developing skin cancer later in life<sup>4</sup>; and

Whereas, Sunscreen has been conclusively shown to protect from a variety of skin cancers<sup>5,6</sup>; and

Whereas, Patients of lower socioeconomic status are less likely to engage in sun-protective behaviors such as sunscreen use, present with later stages of disease, and experience greater mortality from skin cancers linked tightly with sun exposure including melanoma and nonmelanoma cancers<sup>7,8,9</sup>; and

Whereas, Studies have shown that those of low SES who require year-round protection from the sun, such as the homeless and those who spend a significant part of any given day outdoors, may require financial assistance to allow adherence to sun protection guidelines<sup>10</sup>; and

Whereas, The provision of free public sunscreen has been shown to lead to increased systematic application of sunscreen and decrease sunburn occurrence in sun-sensitive individuals<sup>11, 12</sup>; and

Whereas, Clear educational labels placed in areas with sunscreen availability regarding sunburn protection and likely long-term effects of UV also increases adoption of sun-protective behaviors and helps reduce social differentiation of sun-protection behaviors<sup>13,14,15</sup>; and

Whereas, Free public sunscreen programs have been suggested to be partially responsible for the declining rates of melanoma in the northeastern United States compared to the increasing rates nationally<sup>1,16, 27</sup>; and

Whereas, Public sunscreen programs are beginning to gain ground on a local level in the United States<sup>17,18,19,20</sup>; and

Whereas, The CDC supports “interventions in outdoor occupational settings and outdoor recreational and tourism settings to promote sun protective behaviors” such as “providing sunscreen or shade”<sup>21</sup>; and

Whereas, National policy makers support free public sunscreen programs, including the Surgeon General’s Office of the United States<sup>22</sup>; and

Whereas, The American Society for Dermatologic Surgery, the American Academy of Dermatology, and the American Cancer Society each support free public sunscreen programs as a public safety measure<sup>23,24,25,26</sup>; and

Whereas, Current AMA policy H-440.839 supports broad-spectrum sunscreen protection and education programs about the dangers of UV radiation, and AMA policy H-440.841 supports public health intervention programs to reduce population cancer risk; therefore be it

RESOLVED, That our American Medical Association support free public sunscreen programs in public spaces where the population would have a high risk of sun exposure. (New HOD Policy)

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

Received: 08/28/19

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## RELEVANT AMA POLICY

### Protecting the Public from Dangers of Ultraviolet Radiation H-440.839

1. Our AMA encourages physicians to counsel their patients on sun-protective behavior. Tanning Parlors: Our AMA supports: (1) educational campaigns on the hazards of tanning parlors, as well as the development of local tanning parlor ordinances to protect our patients and the general public from improper and dangerous exposure to ultraviolet radiation; (2) legislation to strengthen state laws to make the consumer as informed and safe as possible; (3) dissemination of information to physicians and the public about the dangers of ultraviolet light from sun exposure and the possible harmful effects of the ultraviolet light used in commercial tanning centers; (4) collaboration between medical societies and schools to achieve the inclusion of information in the health curricula on the hazards of exposure to tanning rays; (5) the enactment of federal legislation to: (a) prohibit access to the use of indoor tanning equipment (as defined in 21 CFR 210.40.20 [a][9]) by anyone under the age of 18; and (b) require a United States Surgeon General warning be prominently posted, detailing the positive correlation between ultraviolet radiation, the use of indoor tanning equipment, and the incidence of skin cancer; (6) warning the public of the risks of ultraviolet A radiation (UVA) exposure by skin tanning units, particularly the FDA's findings warning Americans that the use of UVA tanning booths and sun beds pose potentially significant health risks to users and should be discouraged; (7) working with the FDA to ensure that state and local authorities implement legislation, rules, and regulations regarding UVA exposure, including posted warnings in commercial tanning salons and spas; (8) an educational campaign in conjunction with various concerned national specialty societies to secure appropriate state regulatory and oversight activities for tanning parlor facilities, to reduce improper and dangerous exposure to ultraviolet light by patients and general public consumers; and (9) intensified efforts to enforce current regulations. Sunscreens. Our AMA supports: (1) the development of sunscreens that will protect the skin from a broad spectrum of ultraviolet radiation, including both UVA and UVB; and (2) the labeling of sunscreen products with a standardized ultraviolet (UV) logo, inclusive of ratings for UVA and UVB, so that consumers will know whether these products protect against both types of UV radiation. Terms such as low, medium, high and very high protection should be defined depending on standardized sun protection factor level.

2. Our AMA supports sun shade structures (such as trees, awnings, gazebos and other structures providing shade) in the planning of public and private spaces, as well as in zoning matters and variances in recognition of the critical importance of sun protection as a public health measure.

Citation: CCB/CLRPD Rep. 3, A-14; Appended: Res. 403, A-14; Appended: Res. 404, A-19

### Permitting Sunscreen in Schools H-440.841

1. Our AMA supports the exemption of sunscreen from over-the-counter medication possession bans in schools and encourages all schools to allow students to bring and possess sunscreen at school without restriction and without requiring physician authorization.

2. Our AMA will work with state and specialty medical societies and patient advocacy groups to provide advocacy resources and model legislation for use in state advocacy campaigns seeking the removal of sunscreen-related bans at schools and summer camp programs.

Citation: Res. 403, A-13; Appended: Res. 422, A-16

## AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 906  
(I-19)

Introduced by: Medical Student Section

Subject: Ensuring the Best In-School Care for Children with Sickle Cell Disease

Referred to: Reference Committee K

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Whereas, Sickle cell disease (SCD) affects approximately 1 in 100,000 Americans, particularly in communities of color where the incidence is 1 in 365 African Americans and 1 in 16,300 Hispanics in the U.S.<sup>1</sup>; and

Whereas, 1 in 13 African Americans are born with sickle cell trait, making this autosomal recessive disease commonly inherited and highly prevalent in African American families and communities<sup>1</sup>; and

Whereas, Youth with SCD miss on average 20-30 school days per year because of symptoms or complications of the disease<sup>2</sup>; and

Whereas, Adolescents with SCD report having important academic goals, and school absenteeism becomes an impediment of reaching these goals resulting in worse standardized test scores and history of repeated grade levels<sup>3</sup>; and

Whereas, Due to impaired kidney functions, those with SCD need constant access to hydration and liberal access to the bathroom, both of which are frequently monitored and restricted in the classroom<sup>4-7</sup>; and

Whereas, SCD can limit students' abilities to engage in the same intensity of aerobic physical activities as those not impacted by SCD due to increased fatigue and further, exercise-induced acidosis promotes red blood cell sickling<sup>4-8</sup>; and

Whereas, Educators' poor understanding of physical limitations and students' needs for accommodations, such as adequate hydration, can result in increased pain crises or stroke<sup>4-7</sup>; and

Whereas, In a study assessing the needs of educators working with students with chronic illnesses, researchers found that educators felt least supported and trained to work with students suffering from sickle cell disease, cystic fibrosis, and epilepsy<sup>9</sup>; and

Whereas, Studies show that teachers who understand medical conditions such as ADHD, asthma, and allergy tend to use more evidence-based approaches to accommodating students' classroom needs<sup>10-11</sup>; and

Whereas, 25.2% of schools in the United States lack a school nurse, thus recognition and monitoring of potentially emergent medical complications, such as stroke, fall on teachers and non-healthcare staff in many schools<sup>12</sup>; and

Whereas, According to the American School Health Association, school professionals suggested a need for more support when working with students with conditions such as sickle cell disease, cystic fibrosis, and epilepsy<sup>9</sup>; and

Whereas, Existing AMA policy currently “recognizes sickle cell disease (SCD) as a chronic illness, (2) encourages educational efforts directed to health care providers and the public regarding the treatment and prevention of SCD” (H-350.973); and

Whereas, Existing AMA policy currently urges “physicians, physicians-in-training, and medical students to serve as advocates for pediatric patients with diabetes to ensure that they receive the best in-school care, and are not discriminated against, based on current federal and state protections” (H-60.932); and

Whereas, Existing AMA policy currently “(1) urges all schools, from preschool through 12th grade, to: (a) develop Medical Emergency Response Plans” for children at risk for anaphylactic reactions; and “(5) urges physicians to work with parents and schools to ensure that all their patients with a food allergy have an individualized emergency plan” (D-60.976); therefore be it

RESOLVED, That our American Medical Association support the development of an individualized sickle cell emergency care plan by physicians for in-school use, especially during sickle cell crises (New HOD Policy); and be it further

RESOLVED, That our AMA support the education of teachers and school officials on policies and protocols, encouraging best practices for children with sickle cell disease, such as adequate access to the restroom and water, physical education modifications, seat accommodations during extreme temperature conditions, access to medications, and policies to support continuity of education during prolonged absences from school, in order to ensure that they receive the best in-school care, and are not discriminated against, based on current federal and state protections. (New HOD Policy)

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

Received: 08/28/19

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## **RELEVANT AMA POLICY**

### **Sickle Cell Disease H-350.973**

Our AMA: (1) recognizes sickle cell disease (SCD) as a chronic illness, (2) encourages educational efforts directed to health care providers and the public regarding the treatment and prevention of SCD; (3) supports the inclusion of SCD in newborn screening programs and encourages genetic counseling for parents of SCD patients and for young adults who are affected, carriers, or at risk of being carriers; (4) supports ongoing and new research designed to speed the clinical implementation of new SCD treatments; and (5) recommends that SCD research programs have input in the planning stage from the local African American community, SCD patient advocacy groups, and others affected by SCD.

Citation: (CLRPD Rep. 3, I-98; Reaffirmed: CLRPD Rep. 1, A-08; Modified: BOT Rep. 12, A-11)

### **Ensuring the Best In-School Care for Children with Diabetes H-60.932**

Our AMA policy is that physicians, physicians-in-training, and medical students should serve as advocates for pediatric patients with diabetes to ensure that they receive the best in-school care, and are not discriminated against, based on current federal and state protections.

Citation: CSAPH Rep. 4, A-08; Reaffirmed: CSAPH Rep. 01, A-18

### **Childhood Anaphylactic Reactions D-60.976**

Our AMA will: (1) urge all schools, from preschool through 12th grade, to: (a) develop Medical Emergency Response Plans (MERP); (b) practice these plans in order to identify potential barriers and strategies for improvement; (c) ensure that school campuses have a direct communication link with an emergency medical system (EMS); (d) identify students at risk for life-threatening emergencies and ensure these children have an individual emergency care plan that is formulated with input by a physician; (e) designate roles and responsibilities among school staff for handling potential life-threatening emergencies, including administering medications, working with EMS and local emergency departments, and contacting families; (f) train school personnel in cardiopulmonary resuscitation; (g) adopt the School Guidelines for Managing Students with Food Allergies distributed by FARE (Food Allergy Research & Education); and (h) ensure that appropriate emergency equipment to deal with anaphylaxis and acute asthmatic reactions is available and that assigned staff are familiar with using this equipment; (2) work to expand to all states laws permitting students to carry prescribed epinephrine or other medications prescribed by their physician for asthma or anaphylaxis; (3) support increased research to better understand the causes, epidemiology, and effective treatment of anaphylaxis; (4) urge the Centers for Disease Control and Prevention to study the adequacy of school personnel and services to address asthma and anaphylactic emergencies; (5) urge physicians to work with parents and schools to ensure that all their patients with a food allergy have an individualized emergency plan; and (6) work to allow all first responders to carry and administer epinephrine in suspected cases of anaphylaxis.

Citation: (CSAPH Rep. 1, A-07; Modified: CCB/CLRPD Rep. 2, A-14)

## AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 907  
(I-19)

Introduced by: Medical Student Section

Subject: Increasing Access to Gang-Related Laser Tattoo Removal in Prison and Community Settings

Referred to: Reference Committee K

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1 Whereas, Between 2007 and 2012, gang-related homicides were estimated to be approximately  
2 13% of all homicides in the United States<sup>1</sup> and, while national rates of violent crime have been  
3 experiencing historic lows, gang-related homicide rates have stagnated or risen<sup>2</sup> ; and  
4

5 Whereas, Violent crime results in enormous health care costs, criminal justice system  
6 expenditures, and productivity losses, with estimated total costs of \$5.7 million per murder and  
7 \$89,250 per aggravated assault<sup>3</sup>; and  
8

9 Whereas, Public health insurance programs reimburse the majority of insurance claims  
10 pertaining to firearm-related injuries and, by extension, taxpayers bear most of the healthcare  
11 costs relating to these injuries<sup>4</sup>; and  
12

13 Whereas, Gang tattoos present significant barriers to gang detachment and social  
14 reintegration<sup>5</sup>; and  
15

16 Whereas, Gang tattoos increase risk of violent victimization<sup>6</sup>; and  
17

18 Whereas, The AMA Code of Medical Ethics Opinion 8.10 states that “physicians have an ethical  
19 obligation to take actions to avert the harms caused by violence and abuse” for their patients;  
20 and  
21

22 Whereas, Visible<sup>7</sup> and prison<sup>8</sup> tattoos are associated with higher risk for recidivism, putting ex-  
23 offenders at risk for wide-ranging negative health outcomes strongly associated with  
24 incarceration<sup>9</sup>; and  
25

26 Whereas, Visual markers of gang affiliation are stigmatizing and can lead to discrimination in  
27 employment and legal<sup>10</sup> settings; and  
28

29 Whereas, Everyday discrimination mediates the association between former incarceration and  
30 poor mental health outcomes<sup>11</sup>; and  
31

32 Whereas, Tattoo removal can have profound social, psychological, and economic benefits for  
33 formerly incarcerated and gang-affiliated individuals<sup>12,13</sup>; and  
34

35 Whereas, Removal of “branding” tattoos for victims of gang-related human trafficking facilitates  
36 psychosocial healing<sup>15-17</sup>; and



Whereas, Demand for tattoo removal is reflected in the creation of free and low cost community-based tattoo removal programs<sup>18</sup>, including one gang rehabilitation program that performed 11,834 tattoo removal procedures in 2017<sup>19</sup>; and

Whereas, The average national cost for one session of laser tattoo removal procedure in a private physician's office is \$401<sup>20</sup> and an average of 7-10 sessions are required for full removal of one tattoo<sup>21</sup>; and

Whereas, High cost of tattoo removal has led to proliferation of an unregulated market of more inexpensive techniques which pose risks such as burns, dyspigmentation, and scarring<sup>22</sup>; and

Whereas, Tattoo removal services can serve as a bridge to other rehabilitative social, psychological, and educational services and opportunities<sup>23-25</sup>; and

Whereas, There is public support for government-subsidized tattoo removal services for incarcerated and gang-affiliated populations<sup>26</sup>; and

Whereas, Local law enforcement agencies have recognized the value of tattoo removal services for inmates and created prison-based tattoo removal programs<sup>27, 28</sup>; and

Whereas, The AMA has supported expansion of health services in prisons, such as substance abuse treatment (H-430.994, H-430.987) and infant bonding programs (H-430.990), that enable a more successful transition from prison to community settings; therefore be it

RESOLVED, That our American Medical Association support increased access to gang-related tattoo removal in prison and community settings. (New HOD Policy)

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

Received: 08/28/19

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## RELEVANT AMA POLICY

### Definitions of "Cosmetic" and "Reconstructive" Surgery H-475.992

Our AMA: (1) supports the following definitions of "cosmetic" and "reconstructive" surgery:

Cosmetic surgery is performed to reshape normal structures of the body in order to improve the patient's appearance and self-esteem. Reconstructive surgery is performed on abnormal structures of the body, caused by congenital defects, developmental abnormalities, trauma, infection, tumors or disease. It is generally performed to improve function, but may also be done to approximate a normal appearance. (2) Our AMA encourages third party payers to use these definitions in determining services eligible for coverage under the plans they offer or administer. Citation: (CMS Rep. F, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed, A-03; Reaffirmed: CMS Rep. 4, A-13)

### Preventing, Identifying and Treating Violence and Abuse E-8.10

All patients may be at risk for interpersonal violence and abuse, which may adversely affect their health or ability to adhere to medical recommendations. In light of their obligation to promote the well-being of patients, physicians have an ethical obligation to take appropriate action to avert the harms caused by violence and abuse.

To protect patients' well-being, physicians individually should:

- (a) Become familiar with:
  - (i) how to detect violence or abuse, including cultural variations in response to abuse;
  - (ii) community and health resources available to abused or vulnerable persons;
  - (iii) public health measures that are effective in preventing violence and abuse;
  - (iv) legal requirements for reporting violence or abuse.
- (b) Consider abuse as a possible factor in the presentation of medical complaints.
- (c) Routinely inquire about physical, sexual, and psychological abuse as part of the medical history.
- (d) Not allow diagnosis or treatment to be influenced by misconceptions about abuse, including beliefs that abuse is rare, does not occur in "normal" families, is a private matter best resolved without outside interference, or is caused by victims' own actions.
- (e) Treat the immediate symptoms and sequelae of violence and abuse and provide ongoing care for patients to address long-term consequences that may arise from being exposed to violence and abuse.
- (f) Discuss any suspicion of abuse sensitively with the patient, whether or not reporting is legally mandated, and direct the patient to appropriate community resources.
- (g) Report suspected violence and abuse in keeping with applicable requirements. Before doing so, physicians should:
  - (i) inform patients about requirements to report;
  - (ii) obtain the patient's informed consent when reporting is not required by law. Exceptions can be made if a physician reasonably believes that a patient's refusal to authorize reporting is coerced and therefore does not constitute a valid informed treatment decision.
- (h) Protect patient privacy when reporting by disclosing only the minimum necessary information.

Collectively, physicians should:

- (i) Advocate for comprehensive training in matters pertaining to violence and abuse across the continuum of professional education.
- (j) Provide leadership in raising awareness about the need to assess and identify signs of abuse, including advocating for guidelines and policies to reduce the volume of unidentified cases and help ensure that all patients are appropriately assessed.
- (k) Advocate for mechanisms to direct physicians to community or private resources that might be available to aid their patients.
- (l) Support research in the prevention of violence and abuse and collaborate with public health and community organizations to reduce violence and abuse.
- (m) Advocate for change in mandatory reporting laws if evidence indicates that such reporting is not in the best interests of patients.

Issued: 2016

#### **Laser Surgery H-475.988**

The AMA supports the position that revision, destruction, incision or other structural alteration of human tissue using laser is surgery.

Citation: (Res. 316, A-96; Reaffirmed: CSAPH Rep. 3, A-06; Reaffirmed: BOT Rep. 16, A-13)

#### **Prison-Based Treatment Programs for Drug Abuse H-430.994**

Our AMA: (1) encourages the increased application to the prison setting of the principles, precepts and processes derived from drug-free residential therapeutic community experience; and (2) urges state health departments or other appropriate agencies to take the lead in working with correction and substance abuse agencies for the expansion of such prison-based drug-free treatment programs.

Citation: (Sub. Res. 124, I-89; Reaffirmed: Sunset Report, A-00; Modified: CSAPH Rep. 1, A-10; Reaffirmation: I-12)

#### **Opiate Replacement Therapy Programs in Correctional Facilities H-430.987**

1. Our AMA endorses: (a) the medical treatment model of employing opiate replacement therapy (ORT) as an effective therapy in treating opiate-addicted persons who are incarcerated; and (b) ORT for opiate-addicted persons who are incarcerated, in collaboration with the National Commission on Correctional Health Care and the American Society of Addiction Medicine.

2. Our AMA advocates for legislation, standards, policies and funding that encourage correctional facilities to increase access to evidence-based treatment of opioid use disorder, including initiation and continuation of opioid replacement therapy in conjunction with counseling, in correctional facilities within the United States and that this apply to all incarcerated individuals including pregnant women.

3. Our AMA supports legislation, standards, policies, and funding that encourage correctional facilities within the United States to work in ongoing collaboration with addiction treatment physician-led teams, case managers, social workers, and pharmacies in the communities where patients, including pregnant women, are released to offer post-incarceration treatment plans for opioid use disorder, including education, medication for addiction treatment and counseling, and medication for preventing overdose deaths and help ensure post-incarceration medical coverage and accessibility to medication assisted therapy.

Citation: Res. 443, A-05; Reaffirmed: CSAPH Rep. 1, A-15; Appended: Res. 223, I-17

#### **Bonding Programs for Women Prisoners and their Newborn Children H-430.990**

Because there are insufficient data at this time to draw conclusions about the long-term effects of prison nursery programs on mothers and their children, the AMA supports and encourages further research on the impact of infant bonding programs on incarcerated women and their children. The AMA recognizes the prevalence of mental health and substance abuse problems among incarcerated women and continues to support access to appropriate services for women in prisons. The AMA recognizes that a large majority of female inmates who may not have developed appropriate parenting skills are mothers of children under the age of 18. The AMA encourages correctional facilities to provide parenting skills training to all female inmates in preparation for their release from prison and return to their children. The AMA supports and encourages further investigation into the long-term effects of prison nurseries on mothers and their children.

Citation: CSA Rep. 3, I-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmed: CSAPH Rep. 01, A-17

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 908  
(I-19)

Introduced by: Medical Student Section

Subject: Request for Benzodiazepine-Specific Prescribing Guidelines for Physicians

Referred to: Reference Committee K

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Whereas, Benzodiazepines are highly addictive and may cause physical dependence<sup>1</sup>; and

Whereas, From 1999-2016 there has been an almost eightfold rise in mortality rates from benzodiazepine overdoses<sup>2</sup>; and

Whereas, Benzodiazepine overdose rates increased 830% in women aged 30-64 from 1999 to 2017<sup>3</sup>; and

Whereas, The use of benzodiazepines has almost doubled in ambulatory care visits from 2003-2015<sup>4</sup>; and

Whereas, The FDA requires black boxed warnings for the co-prescription of benzodiazepines, opioid analgesics, and opioid-containing cough products<sup>5</sup>; and

Whereas, The rate of co-prescribing benzodiazepines and opioids quadrupled from 2003-2015<sup>4</sup>; and

Whereas, The rate of co-prescribing benzodiazepines and other sedative medications more than doubled from 2003 to 2015<sup>4</sup>; and

Whereas, Some states and cities, such as Texas, Pennsylvania, and New York City, have established guidelines for prescribing benzodiazepines<sup>6-8</sup>; and

Whereas, Some national medical associations, such as the American Family Physician, have various articles about guidelines<sup>9</sup>; and

Whereas, The select state and national medical associations that do have guidelines lack consistency and completeness<sup>10</sup>; and

Whereas, No national guidelines exist to unify overall benzodiazepine prescription guidelines; and

Whereas, The passage of CDC guidelines on opioid prescribing in March 2016 marked a steeper decline in the rate of overall opioid prescriptions<sup>11</sup>; and

Whereas, While the CDC has guidelines for opioid prescriptions it currently does not have any guidelines for benzodiazepine prescriptions<sup>12</sup>; therefore be it

- 1 RESOLVED, That our American Medical Association support the creation of national
- 2 benzodiazepine-specific prescribing guidelines for physicians. (New HOD Policy)

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

Received: 08/28/19

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8. Judicious Prescribing of Benzodiazepines. The New York City Department of Health and Mental Hygiene. 2016; 35(2);13-20.
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10. Dell'Osso, B. et al. Bridging the Gap Between Education and Appropriate Use of Benzodiazepines in Psychiatric Clinical Practice. Neuropsychiatr Dis Treat. 2015; 11:1885-1909.
11. Bohnert, A.S.B. et al. Opioid Prescribing in the United States Before and After the Centers for Disease Control and Prevention's 2016 Opioid Guideline. Ann Intern Med. 2018; 169(6):367-375. CDC.

## RELEVANT AMA POLICY

### Informing the Public & Physicians about Health Risks of Sedative Hypnotics, Especially Rohypnol H-515.968

The AMA re-emphasizes to physicians and public health officials the fact that Rohypnol (a benzodiazepine), other benzodiazepines, and other sedatives and hypnotics carry the risk of misuse, morbidity and mortality. The AMA supports public education and public health initiatives regarding the dangers of the use of sedatives and hypnotics in sexual abuse and rape, especially when mixed with ethanol ingestion.

Citation: Sub. Res. 408, I-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmed: CSAPH Rep. 01, A-17

### Benzodiazepine Education H-100.976

Our AMA encourages physicians interested in the addictive nature of benzodiazepines and their rational use to seek information from appropriate sources.

Citation: (CSA Rep. E, A-92; Amended: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)

### Inappropriate Use of CDC Guidelines for Prescribing Opioids D-120.932

1. Our AMA applauds the Centers for Disease Control and Prevention (CDC) for its efforts to prevent the incidence of new cases of opioid misuse, addiction, and overdose deaths.
2. Our AMA will actively continue to communicate and engage with the nation's largest pharmacy chains, pharmacy benefit managers, National Association of Insurance Commissioners, Federation of State Medical Boards, and National Association of Boards of Pharmacy in opposition to communications being sent to physicians that include a blanket proscription against filing prescriptions for opioids that exceed numerical thresholds without taking into account the diagnosis and previous response to treatment for a patient and any clinical nuances that would support such prescribing as falling within standards of good quality patient care. A report is due back to the House of Delegates at the 2019 Annual Meeting.
3. Our AMA affirms that some patients with acute or chronic pain can benefit from taking opioid pain medications at doses greater than generally recommended in the CDC Guideline for

Prescribing Opioids for Chronic Pain and that such care may be medically necessary and appropriate.

4. Our AMA will advocate against misapplication of the CDC Guideline for Prescribing Opioids by pharmacists, health insurers, pharmacy benefit managers, legislatures, and governmental and private regulatory bodies in ways that prevent or limit patients' medical access to opioid analgesia.

5. Our AMA will advocate that no entity should use MME (morphine milligram equivalents) thresholds as anything more than guidance, and physicians should not be subject to professional discipline, loss of board certification, loss of clinical privileges, criminal prosecution, civil liability, or other penalties or practice limitations solely for prescribing opioids at a quantitative level above the MME thresholds found in the CDC Guideline for Prescribing Opioids.

6. Our AMA: (a) supports balanced opioid-sparing policies that are not based on hard thresholds, but on patient individuality, and help ensure safe prescribing practices, minimize workflow disruption, and ensure patients have access to their medications in a timely manner, without additional, cumbersome documentation requirements; (b) opposes the use of "high prescriber" lists used by national pharmacy chains, pharmacy benefit management companies or health insurance companies when those lists do not provide due process and are used to blacklist physicians from writing prescriptions for controlled substances and preventing patients from having the prescription filled at their pharmacy of choice; and (c) will incorporate into its advocacy that clinical practice guidelines specific to cancer treatment, palliative care, and end of life be utilized in lieu of the CDC's Guideline for Prescribing Opioids for Chronic Pain as per the CDC's clarifying recommendation.

Citation: Res. 235, I-18; Appended: BOT Rep. 22, A-19

#### **A More Uniform Approach to Assessing and Treating Patients for Controlled Substances for Pain Relief D-120.947**

1. Our AMA will consult with relevant Federation partners and consider developing by consensus a set of best practices to help inform the appropriate clinical use of opioid analgesics, including risk assessment and monitoring for substance use disorders, in the management of persistent pain.

2. Our AMA will urge the Centers for Disease Control and Prevention to take the lead in promoting a standard approach to documenting and assessing unintentional poisonings and deaths involving prescription opioids, including obtaining more complete information on other contributing factors in such individuals, in order to develop the most appropriate solutions to prevent these incidents.

3. Our AMA will work diligently with the Centers for Disease Control and Prevention and other regulatory agencies to provide increased leeway in the interpretation of the new guidelines for appropriate prescription of opioid medications in long-term care facilities and in the care of patients with cancer and cancer-related pain, in much the same way as is being done for hospice and palliative care.

Citation: BOT Rep. 3, I-13; Appended: Res. 522, A-16; Modified: Res. 918, I-16; Reaffirmed in lieu of: Res. 803, I-16; Reaffirmation: A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 909  
(I-19)

Introduced by: Resident and Fellow Section

Subject: Decreasing the Use of Oximetry Monitors for the Prevention of Sudden Infant Death Syndrome

Referred to: Reference Committee K

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1 Whereas, A causal relationship between prolonged apnea and sudden infant death syndrome  
2 has not been established; and  
3

4 Whereas, Studies have failed to document any impact of home cardiorespiratory monitoring for  
5 apnea and/or bradycardia on the incidence of sudden infant death syndrome; and  
6

7 Whereas, Home cardiorespiratory monitoring with medical-grade pulse oximeters may be  
8 warranted for infants who have unstable airways, rare medical conditions affecting regulation of  
9 breathing, symptomatic chronic lung disease, or require respiratory support; and  
10

11 Whereas, Home apnea monitors cause unnecessary worry due to false alarms; and  
12

13 Whereas, Parents may actually feel more fear and anxiety if they often use medical equipment  
14 to check on their healthy baby, which can lead to increased parental depression; and  
15

16 Whereas, The most effective ways to reduce the risk of sudden infant death syndrome is to  
17 place baby prone on a firm crib mattress with nothing else in the crib; and  
18

19 Whereas, A recent study in JAMA found that non-FDA regulated oximetry monitors, such as the  
20 Owlet Sock and Baby Vida, performed inconsistently in detecting hypoxemia and also displayed  
21 falsely low pulse rates; and  
22

23 Whereas, False readings from these commercially-available, non-FDA regulated, pulse oximetry  
24 monitors can lead to increased unnecessary use of the medical system; and  
25

26 Whereas, Commercial monitors, such as the Owlet Smart Sock, retails for over \$200, and is  
27 often a recommended baby item by most store baby registries; therefore be it  
28

29 RESOLVED, That our American Medical Association oppose the sale and use of oximetry  
30 monitors to prevent sudden infant death syndrome. (New HOD Policy)

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

Received: 09/04/19

**References:**

- 1 American Academy of Pediatrics. Apnea, sudden infant death syndrome, and home monitoring. Committee on Fetus and Newborn. *Pediatrics* 2003; 111(4): 914-916.
- 2 Bonafide CP, Localio AR, Ferro DF, Orenstein EW, Jamison DT, Lavanchy C, Foglia EE. Accuracy of pulse oximetry-based home baby monitors. *JAMA* 2018; 320(97):717-719.
- 3 Eichenwald EC. Apnea of prematurity. *Pediatrics* 2016; 137(1).
- 4 "The truth about home apnea monitors for SIDs." *Healthy Children*. 22 August 2017  
<<https://www.healthychildren.org/English/ages-stages/baby/sleep/Pages/Home-Apnea-Monitors-for-SIDs.aspx>>.

**RELEVANT AMA POLICY**

**Standardization of Newborn Screening Programs H-245.973**

Our AMA: (1) recognizes the need for uniform minimum newborn screening (NBS) recommendations; and (2) encourages continued research and discussions on the potential benefits and harms of NBS for certain diseases. (CSAPH Rep. 9, A-06; Reaffirmed in lieu of Res. 502, A-09)

**Early Hearing Detection and Intervention H-245.970**

Our AMA: 1) supports early hearing detection and intervention to ensure that every infant receives proper hearing screening, diagnostic evaluation, intervention, and follow-up in a timely manner; and 2) supports federal legislation that provides for the development and monitoring of statewide programs and systems for hearing screening of newborns and infants, prompt evaluation and diagnosis of children referred from screening programs, and appropriate medical, educational, and audiological interventions and follow-up for children identified with hearing loss.

Citation: (Res. 514, A-11; Reaffirmed: CMS Rep. 6, I-15)

**Sudden Infant Death Syndrome H-245.977**

1. The AMA encourages the education of parents, physicians and all other health care professionals involved in newborn care regarding methods to eliminate known Sudden Infant Death Syndrome (SIDS) risk factors, such as prone sleeping, soft bedding and parental smoking.
2. Our AMA will advocate for the appropriate labeling of all infant sleep products, not in compliance with the Safe Infant Sleeping Environment Guidelines, as adopted by the AAP, to adequately warn consumers of the risks of product use and prevent sudden unexpected infant death.
3. Our AMA encourages consumers to avoid commercial devices marketed to reduce the risk of SIDS, including: wedges, positioners, special mattresses, and special sleep surfaces.
4. Our AMA encourages media and manufacturers to follow safe-sleep guidelines in their messaging and advertising.
5. Our AMA encourages further research of infant safe sleeping environment programs, including, but not limited to, the study of the safety and efficacy of boxes.

Citation: (Res. 414, A-95; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15; Appended: Res. 429, A-16; Appended: Res. 407, A-18)

**Infant Mortality D-245.994**

1. Our AMA will work with appropriate agencies and organizations towards reducing infant mortality by providing information on safe sleep positions and preterm birth risk factors to physicians, other health professionals, parents, and child care givers.
2. Our AMA will work with Congress and the Department of Health and Human Services to improve maternal outcomes through: (a) maternal/infant health research at the NIH to reduce the prevalence of premature births and to focus on obesity research, treatment and prevention; (b) maternal/infant health research and surveillance at the CDC to assist states in setting up maternal mortality reviews; modernize state birth and death records systems to the 2003-recommended guidelines; and improve the Safe Motherhood Program; (c) maternal/infant health programs at HRSA to improve the Maternal Child Health Block grant; (d) comparative effectiveness research into the interventions for preterm birth; (e) disparities research into maternal outcomes, preterm birth and pregnancy-related depression; and (f) the development, testing and implementation of quality improvement measures and initiatives.

Citation: (Res. 410, A-10)



AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 910  
(I-19)

Introduced by: Minority Affairs Section

Subject: Ban on Electronic Nicotine Delivery System (ENDS) Products

Referred to: Reference Committee K

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1 Whereas, Vaping or e-cigarettes are common terms--describing products that produce an  
2 aerosolized mixture of nicotine and flavored liquids--that do not encompass all of the products in  
3 this rapidly evolving market. Electronic Nicotine Delivery Systems (ENDS) is a more accurate  
4 term to include personal vaporizers, vape pens, e-cigarettes, e-cigars, e-hookah, vaping  
5 devices, mod systems or pod systems, and whatever new terms might be used for these  
6 incendiary nicotine devices; and  
7

8 Whereas, On December 18, 2018, the U.S. Surgeon General declared e-cigarettes or ENDS an  
9 epidemic, stating, "current e-cigarette use increased 78% among high school students during  
10 the past year, from 11.7% in 2017... In 2018, more than 3.6 million U.S. youth, including 1 in 5  
11 high school students and 1 in 20 middle school students, currently use e-cigarettes";<sup>i</sup> and  
12

13 Whereas, Two deaths and 215 cases of severe pulmonary disease in 25 states are suspected  
14 to be caused by ENDS product use;<sup>ii</sup> prompting the CDC to state, "if you are concerned about  
15 these specific health risks, consider not using e-cigarette products";<sup>iii</sup> and  
16

17 Whereas, The City of San Francisco banned ENDS products, including online sales, citing  
18 safety concerns,<sup>iv</sup> in spite of the fact that JUUL, the company with the market share of ENDS  
19 products, is based in San Francisco; and  
20

21 Whereas, Tobacco is a sacred plant to American Indians that has been highly modified from its  
22 original form to increase the nicotine content. JUUL has approached Tribes, some of the  
23 poorest communities in the U.S., with the offer of hundreds of thousands of dollars to "switch"  
24 their smokers to JUUL products;<sup>v</sup> therefore be it  
25

26 RESOLVED, That our American Medical Association advocate for regulatory, and/or legislative,  
27 and/or legal action at the federal and/or state levels to ban all Electronic Nicotine Delivery  
28 Systems (ENDS) products. (Directive to Take Action)

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

Received: 09/25/19

## RELEVANT AMA POLICY

### Electronic Cigarettes, Vaping, and Health H-495.972

1. Our AMA urges physicians to: (a) educate themselves about electronic nicotine delivery systems (ENDS), including e-cigarettes, be prepared to counsel patients about the use of these products and the potential for nicotine addiction and the potential hazards of dual use with conventional cigarettes, and be sensitive to the possibility that when patients ask about e-cigarettes, they may be asking for help to quit smoking; (b) consider expanding clinical interviews to inquire about "vaping" or the use of e-cigarettes; (c) promote the use of FDA-approved smoking cessation tools and resources for their patients and caregivers; and (d) advise patients who use e-cigarettes to take measures to assure the safety of children in the home who could be exposed to risks of nicotine overdose via ingestion of replacement e-cigarette liquid that is capped or stored improperly.

2. Our AMA: (a) encourages further clinical and epidemiological research on e-cigarettes; (b) supports education of the public on the health effects, including toxins and carcinogens of electronic nicotine delivery systems (ENDS) including e-cigarettes; and (c) recognizes that the use of products containing nicotine in any form among youth, including e-cigarettes, is unsafe and can cause addiction.

3. Our AMA supports legislation and associated initiatives and will work in coordination with the Surgeon General to prevent e-cigarettes from reaching youth and young adults through various means, including, but not limited to, CDC research, education and a campaign for preventing and reducing use by youth, young adults and others of e-cigarettes, and combustible and emerging tobacco products.

Citation: CSAPH Rep. 2, I-14; Modified in lieu of Res. 412, A-15; Modified in lieu of Res. 419, A-15;

Reaffirmed: Res. 421, A-15; Modified: CSAPH Rep. 05, A-18; Reaffirmed: CSAPH Rep. 03, A-19;

Appended: Res. 428, A-19;

### Sales and Distribution of Tobacco Products and Electronic Nicotine Delivery Systems (ENDS) and E-cigarettes H-495.986

H-495.986 Tobacco Product Sales and Distribution

Our AMA:

(1) recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and will actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices, including but not limited to bans and strict restrictions on marketing to minors under the age of 21;

(2) encourages the passage of laws, ordinances and regulations that would set the minimum age for purchasing tobacco products, including electronic nicotine delivery systems (ENDS) and e-cigarettes, at 21 years, and urges strict enforcement of laws prohibiting the sale of tobacco products to minors;

(3) supports the development of model legislation regarding enforcement of laws restricting children's access to tobacco, including but not limited to attention to the following issues: (a) provision for licensure to sell tobacco and for the revocation thereof; (b) appropriate civil or criminal penalties (e.g., fines, prison terms, license revocation) to deter violation of laws restricting children's access to and possession of tobacco; (c) requirements for merchants to post notices warning minors against attempting to purchase tobacco and to obtain proof of age for would-be purchasers; (d) measures to facilitate enforcement; (e) banning out-of-package cigarette sales ("loosies"); and (f) requiring tobacco purchasers and vendors to be of legal smoking age;

(4) requests that states adequately fund the enforcement of the laws related to tobacco sales to minors;

(5) opposes the use of vending machines to distribute tobacco products and supports ordinances and legislation to ban the use of vending machines for distribution of tobacco products;

(6) seeks a ban on the production, distribution, and sale of candy products that depict or resemble tobacco products;

(7) opposes the distribution of free tobacco products by any means and supports the enactment of legislation prohibiting the disbursement of samples of tobacco and tobacco products by mail;

(8) (a) publicly commends (and so urges local medical societies) pharmacies and pharmacy owners who have chosen not to sell tobacco products, and asks its members to encourage patients to seek out and patronize pharmacies that do not sell tobacco products; (b) encourages other pharmacists and pharmacy owners individually and through their professional associations to remove such products from their stores; (c) urges the American Pharmacists Association, the National Association of Retail Druggists, and other pharmaceutical associations to adopt a position calling for their members to remove tobacco products from their stores; and (d) encourages state medical associations to develop lists of pharmacies that have voluntarily banned the sale of tobacco for distribution to their members; and

- (9) opposes the sale of tobacco at any facility where health services are provided; and  
 (10) supports that the sale of tobacco products be restricted to tobacco specialty stores.

Citation: CSA Rep. 3, A-04; Appended: Res. 413, A-04; Reaffirmation A-07; Amended: Res. 817, I-07; Reaffirmation A-08; Reaffirmation I-08; Reaffirmation A-09; Reaffirmation I-13; Reaffirmation A-14; Reaffirmation I-14; Reaffirmation A-15; Modified in lieu of Res. 421, A-15; Modified in lieu of Res. 424, A-15; Reaffirmation I-16; Appended: Res. 926, I-18;

#### **FDA Regulation of Tobacco Products H-495.988**

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

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

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

Citation: CSA Rep. 3, A-04; Reaffirmed: BOT Rep. 8, A-08; Appended: Res. 234, A-12; Reaffirmation A-13; Modified: Res. 402, A-13; Modified: Speakers Rep., A-14; Appended: Res. 420, A-14; Reaffirmation A-15; Modified: CSAPH Rep. 05, A-18; Reaffirmed in lieu of: Res. 412, A-19; Modified: CSAPH Rep. 03, A-19;

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#### **References:**

<sup>i</sup> <https://e-cigarettes.surgeongeneral.gov/documents/surgeon-generals-advisory-on-e-cigarette-use-among-youth-2018.pdf>

<sup>ii</sup> <https://www.cnn.com/2019/09/03/health/ecigarettes-vaping-death-lung-disease-oregon-bn/index.html>

<sup>iii</sup> [https://www.cdc.gov/tobacco/basic\\_information/e-cigarettes/severe-lung-disease.html](https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease.html)

<sup>iv</sup> <https://www.npr.org/sections/health-shots/2019/06/25/735714009/san-francisco-poised-to-ban-sales-of-e-cigarettes>

<sup>v</sup> <https://www.cbsnews.com/news/juul-came-to-a-9th-grade-classroom-and-told-teens-their-products-were-totally-safe-according-to-teens-testimonies/>

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 911  
(I-19)

Introduced by: Young Physicians Section

Subject: Basic Courses in Nutrition

Referred to: Reference Committee K

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Whereas, A 2018 burden of disease collaborators report showed evidence that poor quality diet has been identified as the leading cause of death in the United States<sup>1</sup>; and

Whereas, Health care has shifted from disease management to health promotion and prevention; and

Whereas, “Beginning with medical school the time devoted to nutrition is limited, with an average of 19 total hours over 4 years, and is focused largely on biochemistry and vitamin deficiency states” and nutritional deficiencies (for example, scurvy and beriberi) are not a major problem in the United States<sup>2</sup>; and

Whereas The latest Accreditation Council for Graduate Medical Education common program requirement for residency and fellowship training lack a requirement for physician trainees to learn about nutrition or diet<sup>3</sup>; and

Whereas, Clinical nutrition might not only serve to improve patient health, but also resident and physician wellness through “greater awareness and knowledge of the dietary influences on well-being”<sup>4</sup>; and

Whereas, Clinicians with a foundation in nutrition will be more likely to recognize the importance of diet and make more effective referrals<sup>5</sup>; therefore be it

RESOLVED, That our American Medical Association amend Policy H-150.995, “Basic Courses in Nutrition,” by addition to read as follows:

Basic Courses in Nutrition H-150.995

1. Our AMA encourages effective education in nutrition at the undergraduate, graduate, and postgraduate levels.

2. Our AMA encourages collaboration with appropriate entities to develop and promote relevant nutrition education to enhance patient care and medical trainee education and wellbeing.

3. Our AMA encourages alignment with evidence-based dietary guidelines for food served in medical trainings and medical conferences. (Modify Current HOD Policy)

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

Received: 09/26/19

## RELEVANT AMA POLICY

### [Basic Courses in Nutrition H-150.995](#)

Our AMA encourages effective education **in nutrition** at the undergraduate, graduate, and postgraduate levels.

Sub. Res. 116, A-78 Reaffirmed: CLRPD Rep. C, A-89 Reaffirmed: Sunset Report, A-00

Reaffirmed: CME Rep. 2, A-11 Reaffirmation: A-19

#### References:

1. Mokdad AH, Ballestros K, Echko M, et al. US Burden of Disease Collaborators. The state of US health, 1990-2016: burden of diseases, injuries, and risk factors among US states. *JAMA*. 2018;319(14):1444-1472. doi:10.1001/jama.2018.0158
2. Devries S, Willett W, and Bonow RO. Nutrition Education in Medical School, Residency Training, and Practice. *JAMA*. Published online March 21, 2019. doi:10.1001/jama.2019.1581
3. Accreditation Council for Graduate Medical Education. ACGME Common Program Requirements (Residency). Chicago, IL: Accreditation Council for Graduate Medical Education;2018. Available at <http://www.acgme.org/Portals/0/PFAssets/ProgramRequirements/CPRResidency2019.pdf>. Accessed February 4, 2019.
4. U.S. Department of Health and Human Services. US Department of Agriculture. 2015-2020 Dietary Guidelines for Americans. 8<sup>th</sup> Ed. Washington, DC: Office of Disease Prevention and Health Promotion; 2015. Available at <http://health.gov/dietaryguidelines/2015/guidelines/>. Accessed March 23, 2019.
5. Adams KMBW, Kohlmeier M, and Zeisel S. The state of nutrition education at US medical schools. *J Biomed Educ*. 2015;2015:1-7. doi:10.1155/2015/357627

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 912  
(I-19)

Introduced by: Young Physicians Section

Subject: Improved Emergency Response Planning for Infectious Disease  
Outbreaks

Referred to: Reference Committee K

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Whereas, In the Blueprint list of priority diseases released by the World Health Organization in February 2018, a “Disease X”, or an unexpected infectious disease, was added representing an unknown pathogen with a serious international epidemic potential<sup>1</sup>; and

Whereas, The Centers for Disease Control and Prevention has faced budget cuts of 1.525 billion dollars over the last three fiscal years<sup>2</sup>; and

Whereas, Continued public health funding is fundamental to maintaining essential services to the general population in prevention, outbreak investigation, and emergency response; and

Whereas, Availability of funding for an unexpected infectious disease prior to its clinical presentation would allow for patterned syndromic surveillance; and

Whereas, Early identification of a potential infectious disease outbreak reduces transmission, morbidity, mortality; and

Whereas, Early identification and public health messaging provides education for the general public; therefore be it

RESOLVED, That our American Medical Association encourage hospitals and other entities that collect patient encounter data to report syndromic (i.e., symptoms that appear together and characterize a disease or medical condition) data to public health departments in order to facilitate syndromic surveillance, assess risks of local populations for disease, and develop comprehensive plans with stakeholders to enact actions for mitigation, preparedness, response, and recovery (Directive to Take Action); and be it further

RESOLVED, That our AMA support flexible funding in public health for unexpected infectious disease to improve timely response to emerging outbreaks and build public health infrastructure at the local level with attention to medically underserved areas (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage health departments to develop public health messaging to provide education on unexpected infectious disease. (Directive to Take Action)

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

Received: 09/26/19

## RELEVANT AMA POLICY

### Federal Block Grants and Public Health H-440.912

(1) Our AMA should collaborate with national public health organizations to explore ways in which public health and clinical medicine can become better integrated; such efforts may include the development of a common core of knowledge for public health and medical professionals, as well as educational vehicles to disseminate this information.

(2) Our AMA urges Congress and responsible federal agencies to: (a) establish set-asides or stable funding to states and localities for essential public health programs and services, (b) provide for flexibility in funding but ensure that states and localities are held accountable for the appropriate use of the funds; and (c) involve national medical and public health organizations in deliberations on proposed changes in funding of public health programs.

(3) Our AMA will work with and through state and county medical societies to: (a) improve understanding of public health, including the distinction between publicly funded medical care and public health; (b) determine the roles and responsibilities of private physicians in public health, particularly in the delivery of personal medical care to underserved populations; (c) advocate for essential public health programs and services; (d) monitor legislative proposals that affect the nation's public health system; (e) monitor the growing influence of managed care organizations and other third party payers and assess the roles and responsibilities of these organizations for providing preventive services in communities; and (f) effectively communicate with practicing physicians and the general public about important public health issues.

(4) Our AMA urges state and county medical societies to: (a) establish more collegial relationships with public health agencies and increase interactions between private practice and public health physicians to develop mutual support of public health and clinical medicine; and (b) monitor and, to the extent possible, participate in state deliberations to ensure that block grant funds are used appropriately for health-related programs.

(5) Our AMA urges physicians and medical societies to establish community partnerships comprised of concerned citizens, community groups, managed care organizations, hospitals, and public health agencies to: (a) assess the health status of their communities and determine the scope and quality of population- and personal-based health services in their respective regions; and (b) develop performance objectives that reflect the public health needs of their states and communities.

6. Our AMA: (a) supports the continuation of the Preventive Health and Health Services Block Grant, or the securing of adequate alternative funding, in order to assure preservation of many critical public health programs for chronic disease prevention and health promotion in California and nationwide, and to maintain training of the public health physician workforce; and (b) will communicate support of the continuation of the Preventive Health and Health Services Block Grant, or the securing of adequate alternative funding, to the US Congress.

Citation: CSA Rep. 3, A-96; Reaffirmation A-01; Reaffirmed: CSAPH Rep. 1, A-11; Reaffirmed in lieu of Res. 424, A-11; Appended: Res. 935, I-11; Reaffirmation A-15; Reaffirmed in lieu of: Res. 419, A-19;

### Pandemic Preparedness for Influenza H-440.847

In order to prepare for a potential influenza pandemic, our AMA: (1) urges the Department of Health and Human Services Emergency Care Coordination Center, in collaboration with the leadership of the Centers for Disease Control and Prevention (CDC), state and local health departments, and the national organizations representing them, to urgently assess the shortfall in funding, staffing, vaccine, drug, and data management capacity to prepare for and respond to an influenza pandemic or other serious public health emergency; (2) urges Congress and the Administration to work to ensure adequate funding and other resources: (a) for the CDC, the National Institutes of Health (NIH) and other appropriate federal agencies, to support implementation of an expanded capacity to produce the necessary vaccines and anti-viral drugs and to continue development of the nation's capacity to rapidly vaccinate the entire population and care for large numbers of seriously ill people; and (b) to bolster the infrastructure and capacity of state and local health department to effectively prepare for, respond to, and protect the population from illness and death in an influenza pandemic or other serious public health emergency; (3) urges the CDC to develop and disseminate electronic instructional resources on procedures to follow in an influenza epidemic, pandemic, or other serious public health emergency, which are tailored to the needs of physicians and medical office staff in ambulatory care settings; (4) supports the position that: (a) relevant national and state agencies (such as the CDC, NIH, and the state departments of health) take immediate action to assure that physicians, nurses, other health care professionals, and first responders having direct patient contact, receive any appropriate vaccination in a timely and efficient manner, in order to reassure them that they will have first priority in the event of such a pandemic; and (b) such

agencies should publicize now, in advance of any such pandemic, what the plan will be to provide immunization to health care providers; (6) will monitor progress in developing a contingency plan that addresses future influenza vaccine production or distribution problems and in developing a plan to respond to an influenza pandemic in the United States.

Citation: (CSAPH Rep. 5, I-12; Reaffirmation A-15)

#### **Next Generation Infectious Diseases Diagnostics H-440.834**

1. Our American Medical Association supports strong federal efforts to stimulate early research and development of emerging rapid ID (infectious disease) diagnostic technologies through increased funding for appropriate agencies.
2. Our AMA supports the reduction of regulatory barriers to allow for safe and effective emerging rapid diagnostic tests, particularly those that address unmet medical needs, to more rapidly reach laboratories for use in patient care.
3. Our AMA supports improving the clinical integration of new diagnostic technologies into patient care through outcomes research that demonstrates the impact of diagnostics on patient care and outcomes, educational programs and clinical practice guidelines for health care providers on the appropriate use of diagnostics, and integration of diagnostic tests results into electronic medical records.
4. Our AMA supports efforts to overcome reimbursement barriers to ensure coverage of the cost of emerging diagnostics.

Citation: (Res. 507, A-15; Reaffirmed: CSAPH Rep. 3, I-15)

#### **Public and Private Funding of Prevention Research D-425.999**

Our AMA seeks to work in partnership with the Centers for Disease Control and Prevention, the National Institutes of Health, and other Federal Agencies, the Public Health Community, and the managed care community to ensure that there is a national prevention research agenda.

Citation: Res. 418, I-98; Reaffirmed: CSAPH Rep. 2, A-08; Modified: CSAPH Rep. 01, A-18;

#### **AMA Leadership in the Medical Response to Terrorism and Other Disasters H-130.946**

Our AMA: (1) Condemns terrorism in all its forms and provide leadership in coordinating efforts to improve the medical and public health response to terrorism and other disasters.

(2) Will work collaboratively with the Federation in the development, dissemination, and evaluation of a national education and training initiative, called the National Disaster Life Support Program, to provide physicians, medical students, other health professionals, and other emergency responders with a fundamental understanding and working knowledge of their integrated roles and responsibilities in disaster management and response efforts.

(3) Will join in working with the Department of Homeland Security, the Department of Health and Human Services, the Department of Defense, the Federal Emergency Management Agency, and other appropriate federal agencies; state, local, and medical specialty societies; other health care associations; and private foundations to (a) ensure adequate resources, supplies, and training to enhance the medical and public health response to terrorism and other disasters; (b) develop a comprehensive strategy to assure surge capacity to address mass casualty care; (c) implement communications strategies to inform health care professionals and the public about a terrorist attack or other major disaster, including local information on available medical and mental health services; (d) convene local and regional workshops to share "best practices" and "lessons learned" from disaster planning and response activities; (e) organize annual symposia to share new scientific knowledge and information for enhancing the medical and public health response to terrorism and other disasters; and (f) develop joint educational programs to enhance clinical collaboration and increase physician knowledge of the diagnosis and treatment of depression, anxiety, and post traumatic stress disorders associated with exposure to disaster, tragedy, and trauma.

(4) Believes all physicians should (a) be alert to the occurrence of unexplained illness and death in the community; (b) be knowledgeable of disease surveillance and control capabilities for responding to unusual clusters of diseases, symptoms, or presentations; (c) be knowledgeable of procedures used to collect patient information for surveillance as well as the rationale and procedures for reporting patients and patient information; (d) be familiar with the clinical manifestations, diagnostic techniques, isolation precautions, decontamination protocols, and chemotherapy/prophylaxis of chemical, biological, and radioactive agents likely to be used in a terrorist attack; (e) utilize appropriate procedures to prevent exposure to themselves and others; (f) prescribe treatment plans that may include management of psychological and physical trauma; (g) understand the essentials of risk communication so that they can communicate clearly and nonthreateningly with patients, their families, and the media about issues such as exposure risks and potential preventive measures (e.g., smallpox vaccination); and (h) understand the



role of the public health, emergency medical services, emergency management, and incident management systems in disaster response and the individual health professional's role in these systems.

(5) Believes that physicians and other health professionals who have direct involvement in a mass casualty event should be knowledgeable of public health interventions that must be considered following the onset of a disaster including: (a) quarantine and other movement restriction options; (b) mass immunization/chemoprophylaxis; (c) mass triage; (d) public education about preventing or reducing exposures; (e) environmental decontamination and sanitation; (f) public health laws; and (g) state and federal resources that contribute to emergency management and response at the local level.

(6) Believes that physicians and other health professionals should be knowledgeable of ethical and legal issues and disaster response. These include: (a) their professional responsibility to treat victims (including those with potentially contagious conditions); (b) their rights and responsibilities to protect themselves from harm; (c) issues surrounding their responsibilities and rights as volunteers, and (d) associated liability issues.

(7) Believes physicians and medical societies should participate directly with state, local, and national public health, law enforcement, and emergency management authorities in developing and implementing disaster preparedness and response protocols in their communities, hospitals, and practices in preparation for terrorism and other disasters.

(8) Urges Congress to appropriate funds to support research and development (a) to improve understanding of the epidemiology, pathogenesis, and treatment of diseases caused by potential bioweapon agents and the immune response to such agents; (b) for new and more effective vaccines, pharmaceuticals, and antidotes against biological and chemical weapons; (c) for enhancing the shelf life of existing vaccines, pharmaceuticals, and antidotes; and (d) for improving biological chemical, and radioactive agent detection and defense capabilities.

Citation: (BOT Rep. 26, I-01; Reaffirmed: BOT Rep. 3, I-02; Modified: CSA Rep. 1, I-03; Reaffirmed: CME Rep. 1, I-11; Reaffirmation A-15)

#### **Fund for Public Health Emergency Response H-440.825**

Our AMA supports the reauthorization and appropriation of sufficient funds to a public health emergency fund within the Department of Health and Human Services to facilitate adequate responses to public health emergencies without redistributing funds from established public health accounts.

Citation: Res. 420, A-16;

#### **Global Tracking System of Zoonotic Diseases D-440.940**

Our AMA will work with the American Veterinary Medical Association and other relevant stakeholders to encourage the US Departments of Health and Human Services, Agriculture, Interior, and other appropriate federal and state agencies to take the lead in establishing a robust, coordinated, and effective global surveillance system of zoonotic diseases in humans and syndromic outbreaks in animals, thereby enhancing collaboration of human and animal health sectors and resulting in improved early detection and response.

Citation: Sub. Res. 519, A-10; Reaffirmed: CSAPH Rep. 04, A-19;

#### **References:**

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## AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 913  
(I-19)

Introduced by: Young Physicians Section

Subject: Public Health Impacts and Unintended Consequences of Legalization and Decriminalization of Cannabis for Medicinal and Recreational Use

Referred to: Reference Committee K

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Whereas, AMA Policy D-95.969, "Cannabis Legalization for Medicinal Use," states, in part, that our AMA: "(2) believes that cannabis for medicinal use should not be legalized through the state legislative, ballot initiative, or referendum process;" and

Whereas, AMA Policy H-95.924, "Cannabis Legalization for Recreational Use," states, in part, that our AMA: "(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;" and

Whereas, AMA Policy H-95.923, "Taxes on Cannabis Products," states that "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;" and

Whereas, AMA Policy H-95.952, "Cannabis and Cannabinoid Research," states, in part, that our AMA: "(4) supports research to determine the consequences of long-term cannabis use, especially among youth, adolescents, pregnant women, and women who are breastfeeding; and (5) 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;" and

Whereas, Despite existing AMA policies, "ten states and the District of Columbia have full legalization [of recreational cannabis], and another 23 states permit medicinal uses with permission from a doctor, according to the National Conference of State Legislatures;"<sup>1</sup> and

Whereas, Legalization of both hemp and cannabis have bipartisan support in Congress;<sup>2</sup> and

Whereas, Emerging research in Colorado has shown that "marijuana use during pregnancy, concerns related to marijuana in homes with children, and adolescent use should continue to guide public health education and prevention efforts:

- The percentage of women who use marijuana in pregnancy...is higher among younger women, women with less education, and women with unintended pregnancies.
- Marijuana exposure in pregnancy is associated with decreased cognitive function and attention problems in childhood.
- Unintentional marijuana consumption among children under age 9 continues a slow upward trend, as do emergency visits due to marijuana. Additionally, an estimated 23,000 homes with children in Colorado have marijuana stored potentially unsafely.

- 1 – Marijuana exposures in children can lead to significant clinical effects that require medical  
2 attention;”<sup>3</sup> and  
3

4 Whereas, Dr. Tista Ghosh of the Colorado Department of Public Health and Environment states  
5 that “it’s critical we continue to monitor use in all populations and work to minimize harms that  
6 could result from a variety of causes including unintended poisoning, unsafe driving, and mental  
7 health issues that may be associated with long-term, habitual use;” and  
8

9 Whereas, In Washington State, where recreational marijuana use was decriminalized, “between  
10 2011 and 2013, there was an average of 155 marijuana-related calls per year to the Poison  
11 Control Center; from 2014 to 2016 the average number of calls was 268, a 73% increase;”<sup>4</sup> and  
12

13 Whereas, the Rocky Mountain High Intensity Drug Trafficking Area has been tracking the impact  
14 of marijuana legalization in the state of Colorado, finding that:

- 15 – “Marijuana-related traffic deaths increased 48% in the three-year average (2013-2015)  
16 since Colorado legalized recreational marijuana compared to the three-year average (2010-  
17 2012) prior to legalization;  
18 ○ During the same time, all traffic deaths increased 11%;  
19 – Marijuana-related traffic deaths increased 62% from 71 to 115 persons after recreational  
20 marijuana was legalized in 2013;  
21 – In 2009, Colorado marijuana-related traffic deaths involving operators testing positive for  
22 marijuana represented 10% of all traffic fatalities. By 2015, that number doubled to 21%;  
23 – Emergency department rates likely related to marijuana increased 49% in the two-year  
24 average (2013-2014) since Colorado legalized recreational marijuana compared to the two-  
25 year average prior to legalization (2011-2012);  
26 – Hospital[ization] rates likely related to marijuana increased 32% in the three-year average  
27 (2013-2015) since Colorado legalized recreational marijuana compared to the three-year  
28 average prior to legalization (2010-2012);  
29 – Of the 394 seizures in 2015, there were 36 different states destined to receive marijuana  
30 from Colorado. The most common destinations identified were Missouri, Illinois, Texas,  
31 Iowa, and Florida;”<sup>5</sup> and  
32

33 Whereas, States sharing a border with states that have legalized recreational marijuana may  
34 have increased public health and public safety impacts, with no potential benefits from the tax  
35 revenues associated with that legalization; and  
36

37 Whereas, The AMA Council on Science and Public Health Report 5-I-17, “Clinical Implications  
38 and Policy Consideration of Cannabis Use,” states that “ongoing surveillance to determine the  
39 impact of cannabis legalization and commercialization on public health and safety will be critical.  
40 Surveillance should include but not be limited to the impact on patterns of use, traffic fatalities  
41 and injuries, emergency department visits and hospitalizations, unintentional exposures,  
42 exposure to second-hand smoke, and cannabis-related treatment admissions. At-risk  
43 populations, including pregnant women and children, should be a focus of attention. Continued  
44 evaluation of the effectiveness of regulations developed to ensure public health and safety in  
45 states that have legalized the medical and/or recreational use of cannabis is necessary;”  
46 therefore be it  
47

48 RESOLVED, That our American Medical Association work with interested organizations to  
49 collate existing worldwide data on the public health impacts, societal impacts, and unintended  
50 consequences of legalization and/or decriminalization of cannabis for recreational and medicinal  
51 use, with a report back at the 2020 Interim Meeting (Directive to Take Action); and be it further

1 RESOLVED, That our AMA continue to encourage research on the unintended consequences  
 2 of legalization and decriminalization of cannabis for recreational and medicinal use in an effort  
 3 to promote public health and public safety (Directive to Take Action); and be it further  
 4

5 RESOLVED, That our AMA encourage dissemination of information on the public health  
 6 impacts of legalization and decriminalization of cannabis for recreational and medicinal use, with  
 7 consideration of making links to that information available on the AMA website (Directive to  
 8 Take Action); and be it further  
 9

10 RESOLVED, That our AMA work with interested organizations to lobby Congress to allow more  
 11 sites to conduct research on the risks and benefits of cannabinoid products. (Directive to Take  
 12 Action)

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

Received: 09/26/19

#### RELEVANT AMA POLICY

##### [Cannabis Warnings for Pregnant and Breastfeeding Women H-95.936](#)

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

Citation: Res. 922, I-15; Reaffirmed: CSAPH Rep. 05, I-17;

##### [Taxes on Cannabis Products H-95.923](#)

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

Citation: CSAPH Rep. 05, I-17;

##### [Cannabis and Cannabinoid Research H-95.952](#)

1. Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.

2. Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.

3. Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; c) confirming that cannabis of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support.

4. Our AMA supports research to determine the consequences of long-term cannabis use, especially among youth, adolescents, pregnant women, and women who are breastfeeding.

5. Our AMA urges legislatures to delay initiating the legalization of cannabis for recreational use until further research is completed on the public health, medical, economic, and social consequences of its use.

Citation: 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; Modified: CSAPH Rep. 05, I-17; Reaffirmed in lieu of: Res. 434, A-19;

#### [Cannabis Legalization for Recreational Use H-95.924](#)

Our AMA: (1) believes that cannabis is a dangerous drug and as such is a serious public health concern; (2) believes that the sale of cannabis for 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 to 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; and (6) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use. Citation: CSAPH Rep. 05, I-17;

#### [Cannabis Legalization for Medicinal Use D-95.969](#)

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

Citation: CSAPH Rep. 05, I-17; Appended: Res. 211, A-18;

#### **References:**

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## AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 914  
(I-19)

Introduced by: Indiana

Subject: Nicotine Replacement Therapy for Minors

Referred to: Reference Committee K

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Whereas, The number of children and adolescents under the age of 18 who are using, as well as experiencing exposure to and addiction to tobacco and nicotine, is increasing at an alarming rate; and

Whereas, Most current evidence-based nicotine cessation treatment options are available only to those 18 and older; and

Whereas, Additional treatment options are needed to help young patients; therefore be it

RESOLVED, That our American Medical Association seek immediate and thorough study of the use of all forms of nicotine delivery, as well as all nicotine addiction treatment options in populations under the age of 18 (Directive to Take Action); and be it further

RESOLVED, That our AMA support federal regulation that encourages manufacturers of nicotine addiction treatment therapy approved for adults to examine their products' effects in populations under age 18. (Directive to Take Action)

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

Received: 09/27/19

### RELEVANT AMA POLICY

#### Health Insurance and Reimbursement for Tobacco Cessation and Counseling H-490.916

Our AMA:

(1) (a) continues to support development of an infrastructure for tobacco dependence treatment; (b) will work with the U.S. Public Health Service, particularly the Agency for Health Research and Quality, health insurers, and others to develop recommendations for third party payment for the treatment of nicotine addiction; (c) urges third party payers and governmental agencies involved in medical care to regard and treat nicotine addiction counseling and/or treatment by physicians as an important and legitimate medical service; and (d) supports the ready availability of health insurance coverage and reimbursement for pharmacologic and behavioral treatment of nicotine dependence and smoking cessation efforts;

(2) (a) requests Congress to provide matching funds for Medicaid coverage for evidence-based programs and Food and Drug Administration (FDA)-approved products that lead to smoking cessation; and (b) seeks the requirement that state Medicaid programs, prepaid health plans, and insurance companies provide evidence-based approaches for smoking cessation and nicotine withdrawal, including FDA-approved pharmacotherapy, as part of their standard benefit packages.

CSA Rep. 3, A-04 Reaffirmed: BOT Rep. 8, A-08 Reaffirmation A-11

## AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 915  
(I-19)

Introduced by: American College of Cardiology  
Heart Rhythm Society

Subject: Preventing Death and Disability Due to Particulate Matter Produced by  
Automobiles

Referred to: Reference Committee K

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Whereas, Environmental pollution is the largest cause of premature and preventable death and disability in the world today (Landrigan PJ, Fuller R, Acosta NJR, et al. The Lancet Commission on pollution and health. *Lancet* 2018;391:462-512); and

Whereas, Inextricable evidence documents the adverse health effects of air pollution on climate change and the global environment; and

Whereas, Robust scientific evidence indicates that environmental exposure to toxic nanoparticles (fine particulate matter <2.5 pm), is a direct causal factor in the development of cardiovascular disease, (Rajagopalan S, Al-Kindi SG, Brook RD. Air Pollution and Cardiovascular Disease. *JACC* 2018;72:2054-70. Chen CL, Sera F, Vicedo-Cabrera AM, et al. Ambient Particulate Air Pollution and Daily Mortality in 652 Cities. *N Engl J Med* 2019;381:705-715); and

Whereas, Air pollution and global warming are multi-factorial, longstanding, multinational problems that require comprehensive, widely collaborative solutions; and

Whereas, Gasoline and diesel combustion powered vehicles are a primary source of environmental exposure to these nanoparticles and other disease-causing pollutants including noise (Luscher TF. Noise, pollution, food, or medication: what really matters in primary prevention? *Eur Heart J* 2019;40:563-566), Heritier H, Vienneau D, Foraster M, et al. A systematic analysis of natural effects of transportation noise and air pollution exposure on myocardial infarction mortality: a nationwide cohort study in Switzerland. *Eur Heart J* 2019;40:598-603); and

Whereas, Regulation, reduction and future elimination of gasoline and diesel combustion vehicles has been proposed as a near term, readily achievable means for prevention of cardiovascular diseases which can be implemented while additional comprehensive approaches to reducing air pollution from all sources are developed (Burch I, Gilchrist J. Survey of Global Activity to Phase Out Internal Combustion Engine Vehicles <https://climateprotection.org/wp-content/uploads/2018/09/Survey-in-Global-Activities-to-Phase-Out-ICE-Vehicles-FINAL.pdf>, Schnell J, Naik V, Horowitz LW, et al. Air quality impacts from the electrification of light-duty passenger vehicles in the United States. *Atmospheric Environment*, 2019;208:95); and

Whereas, Automobile manufacturers are aggressively developing electric powered vehicles, and alternatives for quiet, non-polluting, efficient public transportation exist, but funding for these

services competes for funding for freeway construction, air travel and the fossil fuel industry;  
and

Whereas, Reduced exposure to nanoparticles produced by combustion engines may have a beneficial effect in reducing heart disease and cancer of a magnitude similar to that produced by public health programs which reduced tobacco smoking; and

Whereas, Current AMA policy (H-135-998 “Governmental control programs should be implemented primarily at those local, regional, or state levels which have jurisdiction over the respective sources of air pollution and the population and areas immediately affected, and which possess the resources to bring about equitable and effective control,” H-135-999 “...this may be done by federal grants for (1) the development of research activity and (2) the encouragement of local programs for the prevention and control of air pollutants” and D-135-985 “...declare the need for authorities in all states to expeditiously adopt, and implement effective air pollution control strategies to reduce emissions, and this position will be disseminated to state and specialty societies”) should be updated to address urgent policy issues related to environmental exposure to nanoparticles that transcend local, regional and national governmental authority); and

Whereas, Our AMA is responsible for informing our colleagues, our patients and responsible authorities at all levels of society and government as to the medical evidence supporting the direct link between exposure to particulate matter produced by gasoline and diesel powered vehicles to heart and lung disease and cancer, (Dunk JH, Jones DS, Capon A, et al. Human Health on an Ailing Plants – Historical Perspective on Our Future. N Engl J Med 2019;381:778-781); therefore be it

RESOLVED, That our American Medical Association promote policies at all levels of society and government that educate and encourage policy makers to limit or eliminate disease causing contamination of the environment by gasoline and diesel combustion-powered automobiles, advocating for the development of alternative means for automobile propulsion and public transportation. (New HOD Policy)

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

Received: 10/01/19

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- Héritier H, Vienneau D, Foraster M, Eze IC, Schaffner E, de Hoogh K, Thiesse L, Rudzik F, Habermacher M, Köpfli M, Pieren R, Brink M, Cajochen C, Wunderli JM, Probst-Hensch N, Röösli M for the SNC study group. A systematic analysis of mutual effects of transportation noise and air pollution exposure on myocardial infarction mortality: a nationwide cohort study in Switzerland. Eur Heart J 2019;40:598–603.
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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 916  
(I-19)

Introduced by: American College of Cardiology

Subject: Sale of Tobacco in Retail Pharmacies

Referred to: Reference Committee K

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1 Whereas, Smoking tobacco causes heart disease; and

2  
3 Whereas, Ongoing public health efforts to limit tobacco use have had major impact in reducing  
4 the incidence of heart disease; and

5  
6 Whereas, Tobacco smoking continues to be a major cause of heart disease, cancer and lung  
7 disease; and

8  
9 Whereas, Addiction to tobacco smoking often begins in youth; and

10  
11 Whereas, The sale of tobacco products to minors is legally prohibited; and

12  
13 Whereas, The U.S. Food and Drug Administration has identified high rates of sales of tobacco  
14 products to minors by several prominent national retailers, including those who also sell  
15 prescription pharmaceuticals and other healthcare services in their stores; and

16  
17 Whereas, Healthcare providers have a special responsibility to promote the public health and  
18 should not sell addictive products known to cause disease; and

19  
20 Whereas, AMA policy H-500.975 calls for AMA to "...use appropriate lobbying resources to  
21 support programs of anti-tobacco health...."; therefore be it

22  
23 RESOLVED, That our American Medical Association widely publicize opposition to pharmacies  
24 selling tobacco products, especially to minors, and seek active collaboration with other  
25 healthcare professionals through their professional organizations, especially pharmacists, but  
26 including all healthcare team members, to persuade all retailers of prescription pharmaceuticals  
27 to immediately cease selling tobacco products, with a report back at the 2020 Annual Meeting.  
28 (Directive to Take Action)

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

Received: 10/01/19

**RELEVANT AMA POLICY****AMA Corporate Policies on Tobacco H-500.975**

(1) Our AMA: (a) continues to urge the federal government to reduce and control the use of tobacco and tobacco products; (b) supports developing an appropriate body for coordinating and centralizing the Association's efforts toward a tobacco-free society; and (c) will defend vigorously all attacks by the tobacco industry on the scientific integrity of AMA publications.

(2) It is the policy of our AMA to continue to use appropriate lobbying resources to support programs of anti-tobacco health promotion and advertising.

(3) Our AMA's House of Delegates endorses the April 24, 1996, statement by the AMA Secretary-Treasurer that all physicians, health professionals, medical schools, hospitals, public health advocates, and citizens interested in the health and welfare of our children should review their personal and institutional investments and divest of any tobacco holdings (including mutual funds that include tobacco holdings); and specifically calls on all life and health insurance companies and HMOs to divest of any tobacco holdings.

(4) Our AMA defines the Tobacco Industry as companies or corporate divisions that directly produce or purchase tobacco for production or market tobacco products, along with their research and lobbying groups, including the Council for Tobacco Research and the Smokeless Tobacco Research Council. A company or corporate division that does not produce or market tobacco products but that has a tobacco producing company as or among its owners will not be considered a prohibited part of the tobacco industry as long as it does not promote or contribute to the promotion, sale and/or use of tobacco products. If such promotional practices begin, the company will be placed on an "unacceptable for support" list.

(5) Accordingly, it is the policy of our AMA (a) not to invest in tobacco stocks or accept financial support from the tobacco industry; (b) to urge medical schools and their parent universities to eliminate their investments in corporations that produce or promote the use of tobacco and discourage them from accepting research funding from the tobacco industry; (c) to likewise urge all scientific publications to decline such funded research for publication; and (d) to encourage state and county medical societies and members to divest of any and all tobacco stocks.

(6) Our AMA (a) encourages state and local medical societies to determine whether candidates for federal, state and local offices accept gifts or contributions of any kind from the tobacco industry, and publicize their findings to both their members and the public; and (b) urges state and county medical societies and local health professionals along with their allies to support efforts to strengthen state and local laws that require public disclosure of direct and indirect expenditures to influence legislation or ordinances, given recent allegations about tobacco industry strategies.

Citation: (CSA Rep. 3, A-04; Reaffirmed: CSAPH Rep. 1, A-14)

## AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 917  
(I-19)

Introduced by: Medical Student Section

Subject: Supporting Research into the Therapeutic Potential of Psychedelics

Referred to: Reference Committee K

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Whereas, There is a complex cultural and political history regarding psychedelic drugs, which include, among others, mescaline, lysergic acid diethylamide (LSD), psilocybin, and NN-dimethyltryptamine (DMT); and

Whereas, The first legislative limitation of psychedelic use occurred through amendments to the Federal Food, Drug and Cosmetic Act in 1965; and

Whereas, Following this, the Controlled Substances Act (CSA) of 1970 was passed, which places “all substances which were in some manner regulated under existing federal law into one of five schedules”<sup>19</sup>; and

Whereas, Congress established Schedule I for drugs with (1) a high potential for abuse, (2) no accepted medical use in treatment in the United States, and (3) a lack of accepted safety for use under medical supervision<sup>10</sup>; and

Whereas, The major factor distinguishing substances in Schedule I from the others is established and accepted medical use in treatment in the United States<sup>6</sup>; and

Whereas, There is a D.C. Circuit Court precedent stating that a substance or drug with “no currently accepted medical use” should not automatically be placed into Schedule I<sup>9</sup>; and

Whereas, Despite finding in this court ruling, no changes were made as the ruling was filed in dicta, in other words, as an opinion from an authoritative body and not binding, exemplifying the power the Drug Enforcement Agency (DEA) holds over scheduling of substances and an explanation as to why and how the DEA has refused rescheduling of certain substances<sup>6</sup>; and

Whereas, It is argued that scheduling criteria that cannot be consistently followed and that is open to interpretation is fundamentally flawed, making the scheduling of substances by a political law enforcement agency at odds with those that want to study substances for their medical or scientific benefit<sup>6</sup>; and

Whereas, Upon close look at the socio-political environment in the United States at the time of passing the Controlled Substances Act, there is concern over the intention of the law and the consequences that result in limiting the study of psychotropics for medical and scientific purposes; and

Whereas, There is a large amount of evidence that psychedelics exhibit promise as therapeutics for a number of disorders including mood disorders, substance use disorders and headaches, among others; and

Whereas, One such study of more than 900 marginalized women who were at an increased risk of suicide, showed that subjects who used psychedelic drugs were at no significant hazard for suicidal ideation or attempt, while subjects with regular opioid use were at a three times great risk of suicidal ideation<sup>1</sup>; and

Whereas, A systematic review of published clinical treatment studies using psychedelics showed that unipolar mood disorders, the current treatment for which is often suboptimal, can be improved by the psychedelic drugs lysergic acid diethylamide and psilocybin; and

Whereas, Other studies have shown, for example, that long-term ayahuasca use improves a subject's positive percept of health and correlates with health lifestyles, increased personal values, and reduced prescription drug use<sup>11</sup>; and

Whereas, Both psilocybin and ayahuasca may be effective in treating treatment-resistant depression<sup>13,14</sup>; and

Whereas, Ketamine psychedelic therapy may help with alcohol use disorder treatment<sup>7</sup>; and

Whereas, Cluster headaches may be effectively treated by both psilocybin and LSD<sup>18</sup>; and

Whereas, There is evidence that "micro-dosing" of psychedelics led to improved physical functions of connection, contemplation, focus, happiness, productivity and wellness<sup>15</sup>; and

Whereas, It should be noted that the preliminary results surrounding the therapeutic uses of psychedelics are promising, however, the studies done so far have had a limited number of subjects and have not been conducted over long enough time periods to firmly conclude the benefits of these substances; and

Whereas, Major concerns exist over the potential dangers associated with using these substances in research or patient treatment; and

Whereas, Symptoms of using these substances could include increased blood pressure, heart rate, body temperature, pupil size, cortisol, prolactin, oxytocin and epinephrine<sup>17</sup>; and

Whereas, Under current legal and procedural regulations, it is difficult to register to study psychedelic substances through the Drug Enforcement Agency (DEA); and

Whereas, Researchers must submit research protocols to conduct research on Schedule I drugs, and in this manner the DEA continues to be the authority on whether a substance maintains its classification and whether the researchers are allowed to conduct the studies outlined in their protocol pursuant to meeting certain criteria; and

Whereas, As the system currently stands, we are caught in an impasse even though investigators have published evidence to suggest that psychedelics are substances with (1) low potential for abuse, (2) measurable medical use in treatment in the United States, and (3) proven safety while used in clinical trials under medical supervision; therefore be it

RESOLVED, That our American Medical Association call for the status of psychedelics as Schedule I substances be reclassified into a lower schedule class with the goal of facilitating clinical research and developing psychedelic-based medicines (Directive to Take Action); and be it further

1 RESOLVED, That our AMA explicitly support and promote research into the therapeutic  
2 potential of psychedelics to help make a more conducive environment for research, given the  
3 high regulatory and cultural barriers (Directive to Take Action); and be it further

4  
5 RESOLVED, That our AMA support and promote research to determine the benefits and  
6 adverse effects of long-term psychedelic use. (Directive to Take Action)

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

Date Received: 10/01/19

## References:

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16. Rucker, James JH, et al. "Psychedelics in the treatment of unipolar mood disorders: a systematic review." *Journal of Psychopharmacology* 30.12 (2016): 1220-1229.
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19. The Controlled Substances Act. United States Drug Enforcement Administration. 1970.

## RELEVANT AMA POLICY

### FDA Recommendation on Scheduling of Hydrocodone Combination Products D-120.948

Our AMA will issue a public statement to the US Food and Drug Administration urging the FDA to maintain hydrocodone combination products as Schedule III of the Controlled Substances Act.

Citation: Res. 518, A-13;

### Cannabis and Cannabinoid Research H-95.952

1. Our AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease.

2. Our AMA urges that marijuana's status as a federal schedule I controlled substance be reviewed with the goal of facilitating the conduct of clinical research and development of cannabinoid-based medicines, and alternate delivery methods. This should not be viewed as an endorsement of state-based medical cannabis programs, the legalization of marijuana, or that scientific evidence on the therapeutic use of cannabis meets the current standards for a prescription drug product.
3. Our AMA urges the National Institutes of Health (NIH), the Drug Enforcement Administration (DEA), and the Food and Drug Administration (FDA) to develop a special schedule and implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research involving cannabis and its potential medical utility. This effort should include: a) disseminating specific information for researchers on the development of safeguards for cannabis clinical research protocols and the development of a model informed consent form for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of cannabis for clinical research purposes; c) confirming that cannabis of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the DEA who are conducting bona fide clinical research studies that receive FDA approval, regardless of whether or not the NIH is the primary source of grant support.
4. Our AMA supports research to determine the consequences of long-term cannabis use, especially among youth, adolescents, pregnant women, and women who are breastfeeding.
5. Our AMA urges legislatures to delay initiating the legalization of cannabis for recreational use until further research is completed on the public health, medical, economic, and social consequences of its use.

Citation: 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; Modified: CSAPH Rep. 05, I-17; Reaffirmed in lieu of: Res. 434, A-19;

#### **Modernization of the Federal Toxic Substances Control Act (TSCA) of 1976 D-135.976**

Our AMA will: (1) collaborate with relevant stakeholders to advocate for modernizing the Toxic Substances Control Act (TSCA) to require chemical manufacturers to provide adequate safety information on all chemicals and give federal regulatory agencies reasonable authority to regulate hazardous chemicals in order to protect the health of all individuals, especially vulnerable populations; (2) support the public disclosure of chemical use, exposure and hazard data in forms that are appropriate for use by medical practitioners, workers, and the public; and (3) work with members of the Federation to promote a reformed TSCA that is consistent with goals of Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH).

Citation: Res. 515, A-12; Modified: Res. 907, I-13; Reaffirmation I-13; Reaffirmation I-16;

## AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 918  
(I-19)

Introduced by: Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island,  
Vermont, Washington

Subject: Banning Flavors, Including Menthol and Mint, in Combustible and Electronic  
Cigarettes and Other Nicotine Products

Referred to: Reference Committee K

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Whereas, In the United States, tobacco use remains the leading cause of preventable death and disease. Combustible cigarettes, when used as intended, cause the overwhelming majority of tobacco-related disease and are responsible for the death of half of all long-term users;<sup>1</sup> and

Whereas, Menthol cigarettes are at least as dangerous as other cigarettes; and

Whereas, Menthol includes mint, spearmint, and wintergreen; and

Whereas, There are menthol e-cigarette products, including e-cigarette products sold by the major tobacco manufacturers;<sup>2</sup> and

Whereas, The 2018 *National Youth Tobacco Survey*, a representative survey conducted of middle and high school students, showed a 78 percent increase in current e-cigarette use among high school students and a 48 percent increase among middle school students from 2017 to 2018. The total number of middle and high school students currently using e-cigarettes rose to 3.6 million, 1.5 million more children than the previous year. Additionally, 27.7% of high school current e-cigarette users are using the product regularly (on 20 or more days in the past month) and 67.8% are using flavored e-cigarettes;<sup>3</sup> and

Whereas, A state-of-the-art review article on e-cigarette use published in August 2019 by the American Academy of Pediatrics describes that “[t]here are an estimated 15,000 e-cigarette flavors, including products with labels enticing to children and adolescents that imitate cookies, whipped cream, alcoholic beverages, and other dessert flavors” and recommends “[b]an all flavored tobacco products, including mint and menthol;”<sup>4</sup> and

Whereas, Menthol is associated with higher youth initiation rates and lower quit rates;<sup>5,6</sup> and

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<sup>1</sup> Food and Drug Administration. Press announcement. Nov. 15, 2018. Available online: [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm). Accessed Mar 15, 2019.

<sup>2</sup> Ibid.

<sup>3</sup> Food and Drug Administration. Press announcement. Nov. 15, 2018. Available online: [www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm](http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm625884.htm). Accessed Mar 15, 2019.

<sup>4</sup> Walley, S, Wilson, K, et.al. “A Public Health Crisis: Electronic Cigarettes, Vape, and JUUL.” *Pediatrics* Vol 143 (6). August 2019. <https://pediatrics.aappublications.org/content/143/6/e20182741>

<sup>5</sup> Campaign for Tobacco Free Kids; Impact of menthol cigarettes on youth smoking initiation and health disparities. Available online: [www.tobaccofreekids.org/assets/factsheets/0390.pdf](http://www.tobaccofreekids.org/assets/factsheets/0390.pdf). Accessed Mar 17, 2019.

<sup>6</sup> Truth Initiative: facts, stats, and regulations. Available online: <https://truthinitiative.org/news/menthol-facts-stats-and-regulations>. Accessed Mar 17, 2019.

Whereas, The United States Food and Drug Administration (FDA) materials state “Menthol is a flavor additive with a minty taste and aroma that is widely used in consumer and medicinal products due to its reported cooling or painkilling properties. When used in cigarettes, menthol may reduce the irritation and harshness of smoking. However, research suggests menthol cigarettes may be harder to quit than non-menthol cigarettes, particularly among African American smokers.<sup>7</sup> Menthol is also used in other tobacco products, such as cigars, hookah (waterpipe) tobacco, smokeless tobacco (dip, chew, snuff, and snus), and e-cigarettes and other electronic nicotine delivery systems (ENDS)”;<sup>8</sup> and

Whereas, The FDA states that “In the United States:

- More than 19.5 million people are current smokers of menthol cigarettes.
- 85.8 percent of African American smokers, 46 percent of Hispanic smokers, 39 percent of Asian smokers, and 28.7 percent of White smokers smoke menthol cigarettes.
- Youth who smoke are more likely to smoke menthol cigarettes than older smokers.
- More than half of smokers ages 12–17 smoke menthols.”;<sup>9</sup> and

Whereas, Tobacco company marketing has targeted by race, with a focus on the black community for decades, which appears to have caused higher smoking rates of menthol tobacco products in the black community;<sup>10</sup> and

Whereas, The NAACP passed a resolution in 2016 that supports restrictions on menthol sales;<sup>11</sup> and

Whereas, Tobacco companies also focus marketing on the lesbian, gay, bisexual, transgender, and queer/questioning community;<sup>12</sup> and

Whereas, In 2009, tobacco companies successfully lobbied to have menthol excluded from the Family Smoking Prevention and Tobacco Control Act which bans flavor cigarettes;<sup>13</sup> and

Whereas, The U.S. First and Second Circuit Courts have ruled that the Food and Drug Administration has broad preemption language to allow for state and local regulation of flavors;<sup>14</sup> and

<sup>7</sup> Ibid.

<sup>8</sup> Vaporizers, E-Cigarettes, and other Electronic Nicotine Delivery Systems (ENDS). U.S. Food and Drug Administration Website. [www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm](http://www.fda.gov/TobaccoProducts/Labeling/ProductsIngredientsComponents/ucm456610.htm). Updated March 13, 2019. Accessed March 17, 2019.

<sup>9</sup> Menthol and other flavors in tobacco products. U.S. Food and Drug Administration Website. [www.fda.gov/tobaccoproducts/labeling/productsingredientscomponents/ucm2019416.htm#reference](http://www.fda.gov/tobaccoproducts/labeling/productsingredientscomponents/ucm2019416.htm#reference). Updated March 13, 2019. Accessed March 18, 2019.

<sup>10</sup> Ibid.

<sup>11</sup> NCAAP delegates endorse push to say no to menthols. Truth Initiative Website. <https://truthinitiative.org/news/naacp-delegates-endorse-push-say-no-menthols>. Published July 21, 2016. Accessed March 18, 2019.

<sup>12</sup> BIG TOBACCO TARGETS LGBT COMMUNITY WITH MENTHOL CIGARETTES AND PREDATORY ADVERTISING. THINK PROGRESS WEBSITE. [HTTPS://THINKPROGRESS.ORG/BIG-TOBACCO-TARGETS-LGBT-COMMUNITY-WITH-MENTHOL-CIGARETTES-AND-PREDATORY-ADVERTISING-1B059E4E1CDE/](https://thinkprogress.org/big-tobacco-targets-lgbt-community-with-menthol-cigarettes-and-predatory-advertising-1b059e4e1cde/). PUBLISHED MAY 12, 2011. ACCESSED MARCH 16, 2019.

<sup>13</sup> Public Law 111-31 Congress (2009-2010) Family smoking prevention and tobacco control and federal retirement reform. Congress Website. [www.congress.gov/bill/111th-congress/house-bill/1256/text?overview=closed](http://www.congress.gov/bill/111th-congress/house-bill/1256/text?overview=closed). Published June 22, 2009. Accessed March 18, 2019.

<sup>14</sup> Preemption: The biggest challenge to tobacco control. Tobacco Control Legal Consortium Website. <https://publichealthlawcenter.org/sites/default/files/resources/tclc-fs-preemption-tobacco-control-challenge-2014.pdf>. Published October 2014. Accessed March 17, 2019.



1 Whereas, According to the Campaign for Tobacco Free Kids, at least two states and over 200  
2 localities have passed restrictions on the sale of flavored tobacco products, some of which  
3 include restrictions on sales of menthol cigarettes;<sup>15</sup> and  
4

5 Whereas, Last year the FDA issued an advance notice of proposed rulemaking (ANPRM) and  
6 called upon all stakeholders to share data, research, and information to inform their process for  
7 examining the role that flavors--including menthol--play in initiation, use, and cessation of  
8 tobacco products, but fell short of recommending banning all flavors in electronic cigarettes;<sup>16</sup>  
9 and  
10

11 Whereas, According to draft guidance issued in March 2019, the FDA expects manufacturers of  
12 all flavored ENDS products (other than tobacco-, mint-, and menthol-flavored) that remain on  
13 the market under these new conditions to submit premarket applications to the agency by Aug.  
14 8, 2021;<sup>17</sup> and  
15

16 Whereas, A genetic variant found only in people of African descent significantly increases a  
17 smoker's preference for cigarettes containing menthol, an FDA and NIH-funded study found.  
18 The variant of the specific gene is five to eight times more frequent among smokers who use  
19 menthol cigarettes than other smokers;<sup>18</sup> and  
20

21 Whereas, The American Academy of Pediatrics policy statement dated February 2019  
22 recommends that the FDA "Ban all characterizing flavors, including menthol, in e-cigarettes;<sup>19</sup>  
23 and  
24

25 Whereas, Our AMA has consistent policy advocating FDA regulation of tobacco products (FDA  
26 Regulation of Tobacco Products, H-495.988) and policy that "recognizes the use of e-cigarettes  
27 and vaping as an urgent public health epidemic" and "will actively work with the Food and Drug  
28 Administration and other relevant stakeholders to counteract the marketing and use of addictive  
29 e-cigarette and vaping devices "(Sales and Distribution of Tobacco Products and Electronic  
30 Nicotine Delivery Systems (ENDS) and E-cigarettes, H-495.986); and  
31

32 Whereas, Our AMA's policy on FDA Regulatory Jurisdiction over tobacco products (FDA to  
33 Extend Regulatory Jurisdiction Over All Non-Pharmaceutical Nicotine and Tobacco Products,  
34 H-495.973) and Opposition to Addition of Flavors to Tobacco Products (H-495.971) lack  
35 sufficient breadth, specificity and urgency to accomplish the goal of removing all flavors from all  
36 tobacco products, including ENDS immediately; therefore be it

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<sup>15</sup> States and localities that have restricted the sale of flavored tobacco products. Campaign for Tobacco Free Kids, August 14, 2019. <https://www.tobaccofreekids.org/assets/factsheets/0398.pdf>.

<sup>16</sup> Regulation of flavors in tobacco products. Federal Register. The Daily Journal of the United States Government Website. <https://www.federalregister.gov/documents/2018/03/21/2018-05655/regulation-of-flavors-in-tobacco-products>. Published March 15, 2018. Accessed March 17, 2019.

<sup>17</sup> MODIFICATIONS TO COMPLIANCE POLICY FOR CERTAIN DEEMED TOBACCO PRODUCTS. US FOOD AND DRUG ADMINISTRATION WEBSITE. [WWW.FDA.GOV/TOBACCOPRODUCTS/LABELING/RULESREGULATIONSGUIDANCE/UCM633280.HTM](http://WWW.FDA.GOV/TOBACCOPRODUCTS/LABELING/RULESREGULATIONSGUIDANCE/UCM633280.HTM). PUBLISHED MARCH 2019. ACCESSED MARCH 17, 2019.

<sup>18</sup> Kozlitina et al, "An African-specific haplotype in *MRGPRX4* is associated with menthol cigarette smoking." *PLOS Genetics*. February 15, 2019 <https://doi.org/10.1371/journal.pgen.1007916>. Accessed March 16, 2019.

<sup>19</sup> Jennsen and Walley, "E-Cigarettes and Similar Devices." *Pediatrics* Vol143(2). February 2019. <https://doi.org/10.1542/peds.2018-3652>.

1 RESOLVED, That our American Medical Association amend Policy H-495.971, "Opposition to  
2 Addition of Flavors to Tobacco Products," by addition as follows:

3  
4 Our AMA: (1) supports state and local legislation to prohibit the sale or distribution of  
5 all flavored tobacco products, including menthol, mint and wintergreen flavors; (2)  
6 urges local and state medical societies and federation members to support state and  
7 local legislation to prohibit the sale or distribution of all flavored tobacco products;  
8 and (3) encourages the FDA to prohibit the use of all flavoring agents in tobacco  
9 products, which includes electronic nicotine delivery systems as well as combustible  
10 cigarettes, cigars and smokeless tobacco. (Modify Current HOD Policy); and be it  
11 further

12  
13 RESOLVED, That our AMA amend Policy H-495.976, "Opposition to Exempting the  
14 Addition of Menthol to Cigarettes," by addition and deletion as follows:

15  
16 Our AMA: (1) will continue to support a ban on the use and marketing of menthol in  
17 cigarettes all tobacco products as a harmful additive; and (2) encourages and will  
18 assist its members to seek state bans on the sale of menthol cigarettes, electronic  
19 nicotine delivery devices and other tobacco products. (Modify Current HOD Policy)

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

Received: 10/02/19

#### RELEVANT AMA POLICY

##### **Opposition to Addition of Flavors to Tobacco Products H-495.971**

Our AMA: (1) supports state and local legislation to prohibit the sale or distribution of flavored tobacco products; (2) urges local and state medical societies and federation members to support state and local legislation to prohibit the sale or distribution of flavored tobacco products; and (3) encourages the FDA to prohibit the use of flavoring agents in tobacco products, which includes electronic nicotine delivery systems.

Citation: CSAPH Rep. 01, A-18; Modified: Res. 916, I-18;

##### **Opposition to Exempting the Addition of Menthol to Cigarettes H-495.976**

Our AMA: (1) will continue to support a ban on the use and marketing of menthol in cigarettes as a harmful additive; and (2) encourages and will assist its members to seek state bans on the sale of menthol cigarettes.

Citation: BOT Action in response to referred for decision Res. 436, A-08; Modified: CSAPH Rep. 01, A-18;

##### **FDA Regulation of Tobacco Products H-495.988**

1. Our AMA: (A) acknowledges that all tobacco products (including but not limited to, cigarettes, smokeless tobacco, chewing tobacco, and hookah/water pipe tobacco) are harmful to health, and that there is no such thing as a safe cigarette; (B) recognizes that currently available evidence from short-term studies points to electronic cigarettes as containing fewer toxicants than combustible cigarettes, but the use of electronic cigarettes is not harmless and increases youth risk of using combustible tobacco cigarettes; (C) encourages long-term studies of vaping (the use of electronic nicotine delivery systems) and recognizes that complete cessation of the use of tobacco and nicotine-related products is the goal; (D) asserts that tobacco is a raw form of the drug nicotine and that tobacco products are delivery devices for an addictive substance; (E) reaffirms its position that the Food and Drug Administration (FDA) does, and should continue to have, authority to regulate tobacco products, including their manufacture, sale, distribution, and marketing; (F) strongly supports the substance of the August 1996 FDA regulations intended to reduce use of tobacco by children and adolescents as sound public health policy and opposes any federal legislative proposal that would weaken the proposed FDA regulations; (G) urges

Congress to pass legislation to phase in the production of reduced nicotine content tobacco products and to authorize the FDA have broad-based powers to regulate tobacco products; (H) encourages the FDA and other appropriate agencies to conduct or fund research on how tobacco products might be modified to facilitate cessation of use, including elimination of nicotine and elimination of additives (e.g., ammonia) that enhance addictiveness; and (I) strongly opposes legislation which would undermine the FDA's authority to regulate tobacco products and encourages state medical associations to contact their state delegations to oppose legislation which would undermine the FDA's authority to regulate tobacco products.

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

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

Citation: CSA Rep. 3, A-04; Reaffirmed: BOT Rep. 8, A-08; Appended: Res. 234, A-12; Reaffirmation A-13; Modified: Res. 402, A-13; Modified: Speakers Rep., A-14; Appended: Res. 420, A-14; Reaffirmation A-15; Modified: CSAPH Rep. 05, A-18; Reaffirmed in lieu of: Res. 412, A-19; Modified: CSAPH Rep. 03, A-19;

### **Sales and Distribution of Tobacco Products and Electronic Nicotine Delivery Systems (ENDS) and E-cigarettes H-495.986**

H-495.986 Tobacco Product Sales and Distribution

Our AMA:

(1) recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and will actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices, including but not limited to bans and strict restrictions on marketing to minors under the age of 21;

(2) encourages the passage of laws, ordinances and regulations that would set the minimum age for purchasing tobacco products, including electronic nicotine delivery systems (ENDS) and e-cigarettes, at 21 years, and urges strict enforcement of laws prohibiting the sale of tobacco products to minors;

(3) supports the development of model legislation regarding enforcement of laws restricting children's access to tobacco, including but not limited to attention to the following issues: (a) provision for licensure to sell tobacco and for the revocation thereof; (b) appropriate civil or criminal penalties (e.g., fines, prison terms, license revocation) to deter violation of laws restricting children's access to and possession of tobacco; (c) requirements for merchants to post notices warning minors against attempting to purchase tobacco and to obtain proof of age for would-be purchasers; (d) measures to facilitate enforcement; (e) banning out-of-package cigarette sales ("loosies"); and (f) requiring tobacco purchasers and vendors to be of legal smoking age;

(4) requests that states adequately fund the enforcement of the laws related to tobacco sales to minors;

(5) opposes the use of vending machines to distribute tobacco products and supports ordinances and legislation to ban the use of vending machines for distribution of tobacco products;

(6) seeks a ban on the production, distribution, and sale of candy products that depict or resemble tobacco products;

(7) opposes the distribution of free tobacco products by any means and supports the enactment of legislation prohibiting the disbursement of samples of tobacco and tobacco products by mail;

(8) (a) publicly commends (and so urges local medical societies) pharmacies and pharmacy owners who have chosen not to sell tobacco products, and asks its members to encourage patients to seek out and patronize pharmacies that do not sell tobacco products; (b) encourages other pharmacists and pharmacy owners individually and through their professional associations to remove such products from their stores; (c) urges the American Pharmacists Association, the National Association of Retail Druggists, and other pharmaceutical associations to adopt a position calling for their members to remove tobacco products from their stores; and (d) encourages state medical associations to develop lists of pharmacies that have voluntarily banned the sale of tobacco for distribution to their members; and

- (9) opposes the sale of tobacco at any facility where health services are provided; and  
(10) supports that the sale of tobacco products be restricted to tobacco specialty stores.

Citation: CSA Rep. 3, A-04; Appended: Res. 413, A-04; Reaffirmation A-07; Amended: Res. 817, I-07; Reaffirmation A-08; Reaffirmation I-08; Reaffirmation A-09; Reaffirmation I-13; Reaffirmation A-14; Reaffirmation I-14; Reaffirmation A-15; Modified in lieu of Res. 421, A-15; Modified in lieu of Res. 424, A-15; Reaffirmation I-16; Appended: Res. 926, I-18;

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

Our AMA: (1) supports the U.S. Food and Drug Administration's (FDA) proposed rule that would implement its deeming authority allowing the agency to extend FDA regulation of tobacco products to pipes, cigars, hookahs, e-cigarettes and all other non-pharmaceutical tobacco/nicotine products not currently covered by the Federal Food, Drug, and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act; (2) supports legislation and/or regulation of electronic cigarettes and all other non-pharmaceutical tobacco/nicotine products that: (a) establishes a minimum legal purchasing age of 21; (b) prohibits use in all places that tobacco cigarette use is prohibited, including in hospitals and other places in which health care is delivered; (c) applies the same marketing and sales restrictions that are applied to tobacco cigarettes, including prohibitions on television advertising, product placement in television and films, and the use of celebrity spokespeople; (d) prohibits product claims of reduced risk or effectiveness as tobacco cessation tools, until such time that credible evidence is available, evaluated, and supported by the FDA; (e) requires the use of secure, child- and tamper-proof packaging and design, and safety labeling on containers of replacement fluids (e-liquids) used in e-cigarettes; (f) establishes manufacturing and product (including e-liquids) standards for identity, strength, purity, packaging, and labeling with instructions and contraindications for use; (g) requires transparency and disclosure concerning product design, contents, and emissions; and (h) prohibits the use of characterizing flavors that may enhance the appeal of such products to youth; and (3) urges federal officials, including but not limited to the U.S. Food and Drug Administration to: (a) prohibit the sale of any e-cigarette cartridges and e-liquid refills that do not include a complete list of ingredients on its packaging, in the order of prevalence (similar to food labeling); and (b) require that an accurate nicotine content of e-cigarettes, e-cigarette cartridges, and e-liquid refills be prominently displayed on the product alongside a warning of the addictive quality of nicotine.

Citation: Res. 206, I-13; Modified in lieu of Res. 511, A-14; Modified in lieu of Res. 518, A-14; Modified in lieu of Res. 519, A-14; Modified in lieu of Res. 521, A-14; Modified: CSAPH Rep. 2, I-14; Reaffirmation A-15; Reaffirmed in lieu of Res. 412, A-15; Reaffirmed in lieu of Res. 419, A-15; Reaffirmed: Res. 421, A-15; Reaffirmation A-16; Appended: Res. 429, A-18; Modified: CSAPH Rep. 05, A-18;

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 919  
(I-19)

Introduced by: American Thoracic Society

Subject: Raising Awareness of the Health Impact of Cannabis

Referred to: Reference Committee K

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Whereas, As of October 2019, there are 11 states and the District of Columbia that have legalized recreational cannabis to some degree, and 33 states that allow legal cannabis use in medical or other limited circumstances; and

Whereas, Cannabis carries approximately a 10% rate of addiction, or 1 in 6 for users under 18, and that cannabis is the primary substance use disorder in 13% of addiction treatment center admissions nationally;<sup>i,ii</sup> and

Whereas, The medical concerns of cannabis use during adolescence and young adulthood (CW3) include long-term changes to brain development including (1) tetrahydrocannabinol (THC) exposure producing long-term deficits in associative learning and sensorimotor functioning (MB1) (2) cannabis exposure disrupting synaptic and white matter thus leading to adverse emotional and cognitive outcomes (MB2) (3) changes to hippocampal structure as a result of heavy cannabis use which can persist into adulthood (MB3,MB4); and

Whereas, Children and adolescents in states with more liberal marijuana policies are at increased risk for accidental cannabis ingestion and intoxication and need for urgent medical attention (WP1); and

Whereas, Inhaled cannabis is a known threat to respiratory health as (1) inhalation can lead to lung tissue scarring and small vessels damage (2) cannabis smoke contains many of the same toxins, irritants, and carcinogens as tobacco smoke (3) inhaled cannabis can lead to bronchitis, cough, and phlegm production (4) there is a demonstrated risk of acute lung injury, such as seen in the 2019 nationwide outbreak of hundreds of cases of acute lung injury and respiratory failure linked to THC oil inhalation; and

Whereas, Inhaled cannabis has been associated in a small body of research with chronic toxicity and may lead to cancer or chronic lung injury (CW4); and

Whereas, Cannabis use has been negatively associated with mental health including (1) risk of paranoia, anxiety, and disorientation in high use (2) a risk of temporary psychosis (3) increased risk of schizophrenia and (4) worsening comorbid psychosis by increasing relapse rates and worsening psychotic symptoms (CW5); and

Whereas, Synthetic cannabinoids are created to have a stronger binding affinity than natural THC and can be mixed with other agents, and have been linked to acute toxicity and death, including increased death rates in 2014-2015 and toxicity when contaminated with poison in a 2018 outbreak; and

Whereas, Public health concerns from cannabis include but are not limited to driving or operating machinery under the influence of cannabis leading to vehicle accidents and trauma (CW1), accidental ingestions of cannabis by adults or children leading to toxicity (CW2); and

Whereas, According to a 2017 report from The Institute of Medicine, “There are specific regulatory barriers, including the classification of cannabis as a Schedule I substance, that impede the advancement of cannabis and cannabinoid research” (CW6) and

Whereas, Current clinical information available to the medical community about the effects of cannabis is constrained by the limited body of scientific evidence available; and

Whereas, Current reference materials available to the medical community are limited in respect to distinguishing the varieties of cannabis products and drug delivery devices and routes, and the corresponding dosage of cannabinoids in the various products; and

Whereas, Although there is an urgent need for counseling and treatment of cannabis use or overuse, there are few current resources for counseling patients or developing treatment plans; and

Whereas, The word “cannabis” refers to plants within the genus *Cannabis*, including *Cannabis sativa*, *Cannabis indica*, and *Cannabis ruderalis*, but hundreds of alternative and vernacular names such as “marijuana” exist, potentially leading to confusion or misinformation among medical professionals and the public; and

Whereas, The natural cannabinoid chemical derivatives of cannabis, such as THC oil, are also referred to by an extensive and evolving list of names and acronyms, some of which overlap with nomenclature for synthetic cannabinoids, thus leading to confusion or misinformation; therefore be it

RESOLVED, That our American Medical Association coordinate with other health organizations to develop medical resources on the known and anticipated impact of cannabis on human health and on methods for counseling and educating patients who use cannabis and cannabinoids (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for stronger public health messaging on the negative effects of cannabis and cannabinoid inhalation and ingestion (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for urgent regulatory changes necessary to fund and perform research related to cannabis and cannabinoids (Directive to Take Action); and be it further

RESOLVED, That our AMA advocate for minimum purchasing age for cannabis products of at least 21 years old (Directive to Take Action); and be it further

RESOLVED, That our AMA continue to use the term “cannabis” in our policies when referencing cannabis plants, and “cannabis derivatives” or “cannabinoids” when referencing their natural chemical derivatives, but will include the term “marijuana” in physician and public education messaging and materials to improve health literacy (Directive to Take Action); and be it further

1 RESOLVED, That our AMA amend policy H-95.924, "Cannabis Legalization for Recreational  
2 Use," by addition and deletion to read as follows:  
3

4 **Cannabis Legalization for Recreational Use H-95.924**

5 Our AMA: (1) ~~believes-warns~~ that cannabis and cannabinoids can be a threat to  
6 health when inhaled or ingested; (2) ~~advocates that cannabis and cannabinoids are~~  
7 ~~is a dangerous drug and as such is~~ a serious public health concern; (23) ~~believes~~  
8 ~~that warns against~~ the legalized use and sale of cannabis and cannabinoids for  
9 recreational use should not be legalized purposes, due to their negative impact on  
10 human health; (34) ~~discourages warns against cannabis and cannabinoid use for~~  
11 recreational purposes, especially by ~~persons vulnerable to the drug's effects and in~~  
12 ~~high-risk populations such as youth,~~ children and young adults, pregnant women,  
13 and women who are breastfeeding; (45) ~~believes-strongly advocates that states~~  
14 that have already legalized cannabis (for medical or recreational use or both)  
15 should be required to take steps to regulate ~~the product~~ cannabis and  
16 cannabinoids effectively in order to protect public health and safety and that laws  
17 and regulations related to legalized cannabis use should consistently be evaluated  
18 to determine their effectiveness; (56) strongly encourages local, state, and federal  
19 public health agencies to improve surveillance efforts to ensure data is available on  
20 the short- and long-term health effects of cannabis and cannabinoid use; and (67)  
21 supports public health based strategies, rather than incarceration, in the handling  
22 of individuals possessing cannabis or cannabinoids for personal use. (Modify  
23 Current HOD Policy)

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

Received: 10/04/19

References:

- CW1. Boggs, D., Cortes-Briones, J., Surti, T., Luddy, C., Ranganathan, M., Cahill, J., Sewell, A., D'Souza, D., Skosnik, P. (2018). The dose-dependent psychomotor effects of intravenous delta-9-tetrahydrocannabinol ( $\Delta^9$ -THC) in humans Journal of Psychopharmacology 32(12), 1308-1318. <https://dx.doi.org/10.1177/0269881118799953>
- CW2. Wang, G., Lait, M., Deakne, S., Bronstein, A., Bajaj, L., Roosevelt, G. (2016). Unintentional Pediatric Exposures to Marijuana in Colorado, 2009-2015 JAMA Pediatrics 170(9), e160971-e160971. <https://dx.doi.org/10.1001/jamapediatrics.2016.0971>
- CW3. Nader, D., Sanchez, Z. (2017). Effects of regular cannabis use on neurocognition, brain structure, and function: a systematic review of findings in adults The American Journal of Drug and Alcohol Abuse <https://dx.doi.org/10.1080/00952990.2017.1306746>
- CW4. Gates, P., Jaffe, A., Copeland, J. (2014). Cannabis smoking and respiratory health: Consideration of the literature Respiriology 19(5), 655-662. <https://dx.doi.org/10.1111/resp.12298>
- CW5. Schoeler, T., Monk, A., Sami, M., Klamerus, E., Foglia, E., Brown, R., Camuri, G., Altamura, A., Murray, R., Bhattacharyya, S. (2016). Continued versus discontinued cannabis use in patients with psychosis: a systematic review and meta-analysis The Lancet Psychiatry 3(3), 215-225. [https://dx.doi.org/10.1016/s2215-0366\(15\)00363-6](https://dx.doi.org/10.1016/s2215-0366(15)00363-6)
- CW6. Agenda, C., Practice, B., Division, H., Medicine, N. (2017). The Health Effects of Cannabis and Cannabinoids <https://dx.doi.org/10.17226/24625>
- WP1. Wang GS, Roosevelt G, Le lait MC, et al. Association of unintentional pediatric exposures with decriminalization of marijuana in the United States. Ann Emerg Med. 2014;63(6):684-9.
- MB1: Abela AR, Rahbarnia A, Wood S, Lê AD, Fletcher PJ. Adolescent exposure to  $\Delta^9$ -tetrahydrocannabinol delays acquisition of paired-associates learning in adulthood. Psychopharmacology (Berl). 2019;236(6):1875-1886.
- MB2: Dan I. Lubman, Ali Cheetham, Murat Yücel. Cannabis and adolescent brain development. Pharmacology & Therapeutics 2015;148,1-16.
- MB3: Burggren AC, Shirazi A, Ginder N, London ED. Cannabis effects on brain structure, function, and cognition: considerations for medical uses of cannabis and its derivatives. Am J Drug Alcohol Abuse 2019;31:1-17.
- MB4: Burggren AC, Siddarth P, Mahmood Z, London ED, Harrison TM, Merrill DA, Small GW, Bookheimer SY. Subregional hippocampal thickness abnormalities in older adults with a history of heavy cannabis use. Cannabis Cannabinoid Res. 2018;3:242-51.

## RELEVANT AMA POLICY

### Cannabis Legalization for Recreational Use H-95.924

Our AMA: (1) believes that cannabis is a dangerous drug and as such is a serious public health concern; (2) believes that the sale of cannabis for 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; (4) believes states that have already legalized cannabis (for medical or recreational use or both) should be required to 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; and (6) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use. CSAPH Rep. 05, I-17

### Cannabis and Cannabinoid Research H-95.952

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

Citation: 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; Modified: CSAPH Rep. 05, I-17; Reaffirmed in lieu of: Res. 434, A-19

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<sup>i</sup> Centers for Disease Control and Prevention. "Marijuana: How Can It Affect Your Health?" Accessed October 4, 2019. <https://www.cdc.gov/marijuana/health-effects.html>

<sup>ii</sup> Substance Abuse and Mental Health Services Administration, Center for Behavioral Health Statistics and Quality. Treatment Episode Data Set (TEDS): 2017. Admissions to and Discharges from Publicly-Funded Substance Use Treatment. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2019.



AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 920  
(I-19)

Introduced by: American Association of Public Health Physicians

Subject: Maintaining Public Focus on Leading Causes of Nicotine-Related Death

Referred to: Reference Committee K

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Whereas, Our AMA is dedicated to the protection of the public's health; and

Whereas, The protection of the public's health always requires due consideration of quantitative risks, and often requires comparison of competing risks as well; and

Whereas, Direct and indirect exposure to combustible cigarette smoke continues to cause approximately 480,000 deaths each year in the USA, and that number has not decreased significantly for many years<sup>1</sup>; and

Whereas, As of early October 2019, the U.S. outbreak of "vaping-associated pulmonary illness" has risen to approximately 1,080 cases and 19 deaths have been attributed to this outbreak so far<sup>2</sup>; and

Whereas, Americans' rates of combustible cigarette smoking have dropped at an accelerated rate since 2010, since electronic nicotine delivery systems (ENDS) became widely available in the U.S. market<sup>3,4</sup>; and

Whereas, A 2013 Gallup survey of former smokers in the USA, with no attempt to weight the sample by year of quitting, showed that 3% of former smokers in the USA stated that electronic cigarettes were the primary stop-smoking method associated with their successful quitting of combustible cigarettes<sup>5</sup>, and no updates of these data since 2013 are available; and

Whereas, The only large randomized controlled trial of e-cigarettes as a smoking cessation aid was done in Britain, and it showed that British e-cigarettes (used in context of British stop-smoking counseling and cultural context) had stop-smoking results that were clearly superior to those of pharmaceutical nicotine replacement products<sup>6,7</sup>; and

Whereas, There is spirited debate on the real-world effects of e-cigarettes on smoking cessation in the USA<sup>8</sup>; and

Whereas, Public Health England's 2019 update notes that 4.1% of quit attempts assisted by the National Health Service involve the use of electronic cigarettes, and notes on page 95 that, "In every region, quit rates involving the use of an EC were higher than any other type of pharmacotherapy used"<sup>9</sup>; and

Whereas, On August 30, 2019, the U.S. Centers for Disease Control and Prevention (CDC) issued public guidance discouraging use of all ENDS products, regardless of prior nicotine dependence or the purpose of the individual's ENDS use<sup>10</sup>; and

Whereas, Our AMA's public statements during September 2019 basically copied CDC guidance that everyone should stop all use of ENDS products, also regardless of prior nicotine dependence or the purpose of the individual's ENDS use<sup>11,12</sup>; and

Whereas, In late September 2019, CDC modified their guidance to state that, "Adults who use e-cigarettes because they have quit smoking should not return to smoking combustible cigarettes."<sup>13</sup>. However, because this aspect of the CDC recommendation was buried in page three of a five-page report, it seems to have received very little attention in mainstream media or in public consciousness; and

Whereas, In early October 2019, the Atlantic published an analysis by James Hamblin MD noting that the news value of a small number of VAPI-associated deaths is far higher than the news value of a huge number of smoking-associated deaths, reminding us that those trying to save lives by stopping smoking must stay vigilant that this part of our message is not drowned out by other messages<sup>14</sup>; and

Whereas, In early October 2018, a highly respected tobacco industry analyst (who is compensated for the accuracy of her predictions, not for raising the value of any industry stock), cautiously predicted, "While still too early to call, we believe further negative news and an FDA-mandated removal of non-tobacco e-cigarette flavors from the market could result in improved combustible cigarette volumes as vapers potentially return to the cigarette category."<sup>15</sup>; and

Whereas, A significant increase in the number of Americans smoking combustible cigarettes, regardless of the cause of this increase, would result in a public health catastrophe; therefore be it

RESOLVED, That in public statements on nicotine issues, and in discussions with government officials, our AMA seek every reasonable opportunity to remind the American public about: (1) the massive ongoing death toll from combustible cigarettes; (2) the large and solidly demonstrated death toll from environmental tobacco smoke; and (3) the ongoing need for every smoker to find the best possible way to achieve and maintain abstinence from combustible cigarettes. (Directive to Take Action)

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

Received:

<sup>1</sup> [https://www.cdc.gov/tobacco/data\\_statistics/fact\\_sheets/fast\\_facts/index.htm](https://www.cdc.gov/tobacco/data_statistics/fact_sheets/fast_facts/index.htm), accessed September 20, 2019.

<sup>2</sup> <https://www.nytimes.com/2019/10/03/health/vaping-illnesses-cdc.html>, accessed October 4, 2019.

<sup>3</sup> <https://www.cnn.com/2018/11/08/cdc-says-smoking-rates-fall-to-record-low-in-us.html>, accessed October 4, 2019.

<sup>4</sup> <http://tobaccoanalysis.blogspot.com/2019/09/e-cigarettes-are-gateway-to-smoking-so.html>, accessed September 12, 2019.

<sup>5</sup> <https://news.gallup.com/poll/163763/smokers-quit-tried-multiple-times.aspx>, accessed October 4, 2019.

<sup>6</sup> <https://www.nejm.org/doi/10.1056/NEJMoa1808779>, accessed October 4, 2019.

<sup>7</sup> <https://www.health.harvard.edu/blog/can-vaping-help-you-quit-smoking-2019022716086>, accessed October 4, 2019.

<sup>8</sup> <https://www.cnn.com/2019/07/15/health/e-cigarettes-quit-smoking-study/index.html>, accessed October 4, 2019.

<sup>9</sup> [https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment\\_data/file/821179/Vaping\\_in\\_England\\_an\\_evidence\\_update\\_February\\_2019.pdf](https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/821179/Vaping_in_England_an_evidence_update_February_2019.pdf), accessed October 7, 2019.

<sup>10</sup> <https://emergency.cdc.gov/han/han00421.asp?deliveryName=DM8038>, accessed October 4, 2019.

<sup>11</sup> <https://www.ama-assn.org/press-center/ama-statements/ama-urges-public-avoid-e-cigarette-use-amid-lung-illness-outbreak>, accessed September 9, 2019.

<sup>12</sup> <https://www.npr.org/2019/09/12/760077445/trump-calls-for-ban-on-non-tobacco-flavored-vaping-products>, accessed September 16, 2019.

<sup>13</sup> [https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6839e1-h.pdf?deliveryName=USCDC\\_921-DM9775](https://www.cdc.gov/mmwr/volumes/68/wr/pdfs/mm6839e1-h.pdf?deliveryName=USCDC_921-DM9775), accessed September 27, 2019.

<sup>14</sup> <https://www.theatlantic.com/health/archive/2019/10/how-dangerous-vaping/599209/>, accessed October 2, 2019.

<sup>15</sup> [https://www.journalnow.com/business/e-cigarette-sales-begin-to-cool-as-public-health-warnings/article\\_3eb0c42e-2e70-5bbe-84ae-7e2835c7ebee.html](https://www.journalnow.com/business/e-cigarette-sales-begin-to-cool-as-public-health-warnings/article_3eb0c42e-2e70-5bbe-84ae-7e2835c7ebee.html), accessed October 3, 2019.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 921  
(I-19)

Introduced by: Thomas J. Madejski, MD, Delegate

Subject: Vaping in New York State and Nationally

Referred to: Reference Committee K

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Whereas, Recent reports of lung illness associated with the use of vaporization devices have killed or injured multiple people in New York and throughout the nation; and

Whereas, The addiction industry, which includes tobacco, alcohol and now marijuana companies, has been allowed to sell products for human consumption without rigorous study on long term positive and negative effects and patient safety by subverting the FDA approval process; and

Whereas, In the context of a crisis of youth vaping and addiction to nicotine and other substances driven by the addiction industry; and

Whereas, Vaporization delivery device manufacturers such as JUUL have significant ownership by tobacco companies and marijuana companies and plan to expand use of addictive products across all segments of the adult and indirectly the adolescent population despite their protestations to the same; and

Whereas, In the interest of patient safety, and with an abundance of caution, acknowledging incomplete data on the etiology of acute and chronic lung injury associated with vaporization devices and the various substances which can be vaporized, therefore be it

RESOLVED, That our American Medical Association cooperate with the Medical Society of the State of New York (MSSNY) to express our gratitude to New York Governor Andrew Cuomo and Commissioner of the Department of Health Howard Zucker, MD for their prompt action to protect patients by banning the sale of flavored e cigarettes (Directive to Take Action); and be it further

RESOLVED, That our AMA cooperate with MSSNY to express our gratitude to Governor Cuomo and Health Commissioner Zucker for their advice to consumers to avoid vaporization of medical marijuana available under the New York State medical marijuana program (Directive to Take Action); and be it further

RESOLVED, That our AMA cooperate with MSSNY to recommend to Governor Cuomo, Commissioner Zucker, and New York State Legislators, and in conjunction with other State Medical Societies, other State Executives, Health Commissioners and Legislatures to take further action to protect consumers from exposure to vaporized products with a moratorium on dispensing of vaporized products to new certificate holders for medical marijuana until data on the long term safety of vaporized marijuana is available (Directive to Take Action); and be it further

- 1 RESOLVED, That our AMA cooperate with MSSNY to recommend that state and federal
- 2 representatives work to reschedule marijuana and its' component substances to Schedule II
- 3 controlled substance to reduce barriers to further study on the efficacy and harms of various
- 4 marijuana products. (Directive to Take Action)

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

Received: 10/04/19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 922  
(I-19)

Introduced by: Michigan

Subject: Understanding the Effects of PFAS on Human Health

Referred to: Reference Committee K

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Whereas, Perfluoroalkyl and polyfluoroalkyl chemicals (PFAS) are a group of synthetic compounds that have been used in thousands of industrial applications and consumer products worldwide and are recognized by the Centers for Disease Control and Prevention (CDC) as substances toxic to human health; and

Whereas, The Environmental Protection Agency (EPA) has found PFAS in water and soil nationwide, termed PFAS an “emerging contaminant,” and set health advisory levels for two specific PFAS chemicals at 70 parts per trillion (ppt); and

Whereas, Michigan declared a state of emergency in July 2018 for Kalamazoo County for PFAS levels over 20 times higher than the EPA safety limit; and

Whereas, As of February 2019, 43 sites in Michigan detected PFAS, including PFAS levels higher than 70 ppt in six schools, and PFAS in the drinking water that serves more than two million Michigan residents; and

Whereas, The CDC Agency for Toxic Substances and Disease Registry (ATSDR) recommended in June 2018 reducing the minimum risk levels of PFAS ten-fold, from 70 ppt to 7 ppt, because of the chemicals’ negative health effects; and

Whereas, PFAS bioaccumulate in human tissues and bodily fluids through contaminated foods, drinking water and consumer products, with half-life estimates ranging from 2.3 to 12 years based on the type of chemical; and

Whereas, PFAS cross the placenta barrier, are transmitted through breast milk and are consistently associated with fetal and postnatal growth and immune function in epidemiologic studies; and

Whereas, PFAS serum levels are negatively associated with vaccine antibody concentrations in adolescents, which may be a result of an inhibited initial vaccination response or a greater waning of immunity over time; and

Whereas, Many additional research studies have suggested that PFAS in humans may increase risk of hypertension and pre-eclampsia during pregnancy, increase cholesterol levels, increase risk of thyroid disease, decrease fertility, and increase risk of kidney disease; and

Whereas, While current research has been limited to a few PFAS chemicals, more than 4000 PFAS chemicals have been manufactured by humans; hundreds of these have been detected in environmental samples and there are not currently assays to detect them all; and

1 Whereas, The EPA has not lowered the recommended PFAS health advisory levels since the  
2 release of the aforementioned June 2018 CDC report; and  
3

4 Whereas, Despite CDC and EPA recommendations, only seven states have developed water  
5 guideline levels for PFAS, but their advisory levels range from 13 to 1000 ppt for only a few  
6 PFAS chemicals; therefore be it  
7

8 RESOLVED, That our American Medical Association advocate for continued research on the  
9 impact of perfluoroalkyl and polyfluoroalkyl chemicals on human health (Directive to Take  
10 Action); and be it further  
11

12 RESOLVED, That our AMA advocate for states to minimally follow guidelines regarding levels of  
13 perfluoroalkyl and polyfluoroalkyl chemicals recommended by the Centers for Disease Control  
14 and Prevention and the Environmental Protection Agency. (Directive to Take Action)

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

Received: 10/03/19

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## **RELEVANT AMA POLICY**

### **Modern Chemicals Policies H-135.942**

Our AMA supports: (1) the restructuring of the Toxic Substances Control Act to serve as a vehicle to help federal and state agencies to assess efficiently the human and environmental health hazards of industrial chemicals and reduce the use of those of greatest concern; and (2) the Strategic Approach to International Chemicals (SAICM) process leading to the sound management of chemicals throughout their life-cycle so that, by 2020, chemicals are used and produced in ways that minimize adverse effects on human health and the environment.

Citation: Sub. Res. 404, A-08; Reaffirmation A-10; Reaffirmed: CSAPH Rep. 5, A-11; Reaffirmation I-16; Reaffirmed in lieu of: Res. 505, A-19;

### **Modernization of the Federal Toxic Substances Control Act (TSCA) of 1976 D-135.976**

Our AMA will: (1) collaborate with relevant stakeholders to advocate for modernizing the Toxic Substances Control Act (TSCA) to require chemical manufacturers to provide adequate safety information on all chemicals and give federal regulatory agencies reasonable authority to regulate hazardous chemicals in order to protect the health of all individuals, especially vulnerable populations; (2) support the public disclosure of chemical use, exposure and hazard data in forms that are appropriate for use by medical practitioners, workers, and the public; and (3) work with members of the Federation to promote a reformed TSCA that is consistent with goals of Registration, Evaluation, Authorisation, and Restriction of Chemicals (REACH).

Citation: Res. 515, A-12; Modified: Res. 907, I-13; Reaffirmation I-13; Reaffirmation I-16;

### **Modern Chemicals Policies D-135.987**

Our AMA: (1) will call upon the United States government to implement a national modern, comprehensive chemicals policy that is in line with current scientific knowledge on human and environmental health, and that requires a full evaluation of the health impacts of both newly developed and industrial chemicals now in use; and (2) encourages the training of medical students, physicians, and other health professionals about the human health effects of toxic chemical exposures.

Citation: Sub. Res. 404, A-08; Reaffirmation A-10; Reaffirmation I-16;

### **Safer Chemical Policies D-135.973**

Our AMA will review the recommendations of the National Academies of Sciences with respect to chemical policy reform.

Citation: (Res. 415, A-14)

## AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 923  
(I-19)

Introduced by: Michigan

Subject: Support Availability of Public Transit Systems

Referred to: Reference Committee K

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1 Whereas, Existing American Medical Association policy states that “climate changes will create  
2 conditions that affect public health, with disproportionate impacts on vulnerable populations,  
3 including children, the elderly, and the poor” (H-135.938), and supports “maximum feasible  
4 reduction of all forms of air pollution” (H-135.998); and  
5

6 Whereas, A shift from personal car use to public transport use can cause a six-fold decrease in  
7 greenhouse gas emissions; and  
8

9 Whereas, The Lancet Commission on Pollution and Health has concluded that pollution can be  
10 controlled by switching to an economy that relies on public transport and discourages private  
11 car use in cities; and  
12

13 Whereas, Cities whose citizens utilize their public transit networks, averaging 50 or more transit  
14 trips per year, have half the average fatalities from traffic compared to cities with an average of  
15 20 transit trips per year; and  
16

17 Whereas, A study that modeled the potential health effects of switching 40 percent of private  
18 vehicle transport to alternative transport in a 1.1-million-person metropolitan area showed that  
19 per year 508 deaths were prevented due to increased physical activity, 21 deaths were  
20 prevented by avoiding traffic fatalities, and 13 deaths were prevented due to improved air  
21 conditions; and  
22

23 Whereas, The implementation of a new transit system has been shown to generate new  
24 physical activity and decrease body mass indexes among new users; and  
25

26 Whereas, In addition to improving air quality and reducing negative effects on the environment,  
27 public transport can increase health care access for underserved populations and geographical  
28 areas; and  
29

30 Whereas, Rural cancer patients who lack a car are often unable to access their radiation and  
31 chemotherapy treatments in neighboring towns and cities; and  
32

33 Whereas, 78 percent of people with disabilities have challenges accessing transportation for  
34 health care services, and public transportation improves the quality of life and independence of  
35 young adults with disabilities; and  
36

37 Whereas, Ride share programs such as Uber are not legally required to adhere to Americans  
38 With Disabilities Act guidelines, which eliminates yet another mode of transportation for people  
39 with disabilities; and



Whereas, Use of public transport by the elderly is associated with decreased depressive symptoms, reduced feelings of loneliness, increased contact with friends and children, and increased volunteering; therefore be it

RESOLVED, That our American Medical Association amend current policy H-135.939, "Green Initiatives and the Health Care Community," by addition and deletion as follows:

Our AMA supports: (1) responsible waste management and clean energy production policies that minimize health risks, 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) the~~ establishment, expansion, and continued maintenance of affordable, reliable public transportation; and (6) community-wide adoption of 'green' initiatives and activities by organizations, businesses, homes, schools, and government and health care entities (New HOD Policy); and be it further

RESOLVED, That our AMA amend current policy H-425.993, "Health Promotion and Disease Prevention," by addition and deletion as follows:

The AMA (1) reaffirms its current policy pertaining to the health hazards of tobacco, alcohol, accidental injuries, unhealthy lifestyles, and all forms of preventable illness; (2) advocates intensified leadership to promote better health through prevention; (3) believes that preventable illness is a major deterrent to good health and accounts for a major portion of our country's total health care expenditures; (4) actively supports appropriate scientific, educational and legislative activities that have as their goals: (a) prevention of smoking and its associated health hazards; (b) avoidance of alcohol abuse, particularly that which leads to accidental injury and death; (c) reduction of death and injury from vehicular and other accidents; and (d) encouragement of healthful lifestyles and personal living habits; ~~and (5) advocates that health be considered one of the goals in transportation planning and policy development including but not limited to the establishment, expansion, and continued maintenance of affordable, reliable public transportation; and (6)~~ strongly emphasizes the important opportunity for savings in health care expenditures through prevention. (Modify Current HOD Policy)

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

Received: 10/03/19

#### Sources:

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## **RELEVANT AMA POLICY**

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

Our AMA supports: (1) responsible waste management and clean energy production policies that minimize health risks, 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.

Citation: CSAPH Rep. 1, I-08; Reaffirmation A-09; Reaffirmed in lieu of Res. 402, A-10; Reaffirmed in lieu of: Res. 504, A-16; Modified: Res. 516, A-18;

### **Health Promotion and Disease Prevention H-425.993**

The AMA (1) reaffirms its current policy pertaining to the health hazards of tobacco, alcohol, accidental injuries, unhealthy lifestyles, and all forms of preventable illness; (2) advocates intensified leadership to promote better health through prevention; (3) believes that preventable illness is a major deterrent to good health and accounts for a major portion of our country's total health care expenditures; (4) actively supports appropriate scientific, educational and legislative activities that have as their goals: (a) prevention of smoking and its associated health hazards; (b) avoidance of alcohol abuse, particularly that which leads to accidental injury and death; (c) reduction of death and injury from vehicular and other accidents; and (d) encouragement of healthful lifestyles and personal living habits; and (5) strongly emphasizes the important opportunity for savings in health care expenditures through prevention.

Citation: Presidential Address, A-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: BOT Rep. 8, I-06; Reaffirmed: CSAPH Rep. 01, A-16;

See also:

[Global Climate Change and Human Health H-135.938](#)

[AMA Position on Air Pollution H-135.998](#)

[8.11 Health Promotion and Preventive Care](#)

[11.1.4 Financial Barriers to Health Care Access](#)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 924  
(I-19)

Introduced by: Michigan

Subject: Update Scheduled Medication Classification

Referred to: Reference Committee K

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1 Whereas, Many of the reforms adopted through legislation and the development of guidelines  
2 have complicated the prescribing of both opioids and non-opioid scheduled medications; and  
3

4 Whereas, Substances are placed in their respective controlled substance schedules based on  
5 whether they have a currently accepted medical use in treatment in the United States, their  
6 relative abuse potential, and likelihood of causing dependence when abused; and  
7

8 Whereas, Currently, the controlled substance schedules do not differentiate between opioid  
9 containing and non-opioid containing controlled substances; and  
10

11 Whereas, There are options for differentiating opioids from non-opioids such as dividing each  
12 schedule into two classes (e.g., 3-O for opioids and 3-N for non-opioids); therefore be it  
13

14 RESOLVED, That our American Medical Association amend current policy D-120.979, "DEA  
15 Regulations and the Ability of Physicians to Prescribe Controlled Medication Rationally, Safely,  
16 and Without Undue Threat of Prosecution," by addition as follows:  
17

18 Our AMA supports ongoing constructive dialogue between the DEA and clinicians,  
19 including physicians, regarding: (1) a proper balance between the needs of patients  
20 for treatment and the needs of the government to provide oversight and regulation to  
21 minimize risks to public health and safety; and (2) potential changes to the controlled  
22 substances schedules to make it easier to differentiate opioid containing controlled  
23 substances from non-opioid controlled substances within each schedule. (Modify  
24 Current HOD Policy)

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

Received: 10/03/19

## **RELEVANT AMA POLICY**

### **DEA Regulations and the Ability of Physicians to Prescribe Controlled Medication Rationally, Safely, and Without Undue Threat of Prosecution D-120.979**

Our AMA supports ongoing constructive dialogue between the DEA and clinicians, including physicians, regarding a proper balance between the needs of patients for treatment and the needs of the government to provide oversight and regulation to minimize risks to public health and safety.

Citation: (Res. 836, I-04; Appended: Sub. Res. 502, A-05; Modified: CSAPH Rep. 1, A-15)

### **Promoting Pain Relief and Preventing Abuse of Controlled Substances D-120.971**

Our AMA will:

- (1) urge the Drug Enforcement Administration (DEA) to publicly restate their commitment to balance in promoting pain relief and preventing abuse of pain medications;
- (2) support an ongoing constructive dialogue among the DEA and physician groups to assist in establishing a clinical practice environment that is conducive to pain management and the relief of suffering, while minimizing risks to public health and safety from drug abuse or diversion;
- (3) strongly urge that the DEA's upcoming recitation of the pertinent legal principles relating to the dispensing of controlled substances for the treatment of pain maintain a patient-centered focus, including reaffirmation of its previous interpretation of law to permit practitioners to issue a series of prescriptions marked "do not fill" until a later date; and
- (4) strongly urge that the DEA should promulgate, in consultation with relevant medical specialty societies and patient advocacy groups, a rational and realistic set of FAQs to assist in providing education to health care practitioners and law enforcement and regulatory personnel about appropriate pain management, and measures to be taken to minimize drug abuse and diversion.

Citation: BOT Rep. 3, A-06; Reaffirmation A-13; Reaffirmed: BOT Rep. 19, A-16; Reaffirmation: A-19;

### **Curtailing Prescription Drug Abuse While Preserving Therapeutic Use - Recommendations for Drug Control Policy H-95.979**

Our AMA (1) opposes expansion of multiple-copy prescription programs to additional states or classes of drugs because of their documented ineffectiveness in reducing prescription drug abuse, and their adverse effect on the availability of prescription medications for therapeutic use; (2) supports continued efforts to address the problems of prescription drug diversion and abuse through physician education, research activities, and efforts to assist state medical societies in developing proactive programs; and (3) encourages further research into development of reliable outcome indicators for assessing the effectiveness of measures proposed to reduce prescription drug abuse.

Citation: (BOT Rep. PP, A-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10; Reaffirmation A-15)

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 925  
(I-19)

Introduced by: California

Subject: Suspending Sales of Vaping Products / Electronic Cigarettes Until FDA Review

Referred to: Reference Committee K

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Whereas, Nationwide, the number of cases of confirmed and probable vaping-associated lung illnesses has risen to 1,080 across 48 states, with 19 reported deaths, according to the Centers for Disease Control and Prevention (CDC) and therefore, the CDC has warned people to avoid vaping altogether; and

Whereas, Vaping and electronic cigarettes are also increasingly being shown to have negative health impacts including harm to cardiovascular function, addiction to nicotine, secondhand exposure to harmful chemicals, progression to use of tobacco products, and more, with adolescent use skyrocketing in recent years, even erasing more than a decade of progress in reducing youth tobacco consumption; and

Whereas, The U.S. Food and Drug Administration (FDA) recently strengthened its warning to consumers to stop using vaping products containing THC amid more than 1,000 reports of lung injuries--including some resulting in deaths--following the use of vaping products; and

Whereas, The mass marketing of vaping products has been shown in some ways to resemble long time tobacco marketing practices, including downplaying risks and targeting young people, despite restrictions on sale to youth; and

Whereas The explosion of the vaping products industry and marketing has somewhat caught health officials and researchers off-guard, with a "catch-up" scenario playing out as regulation and education lag behind the explosion in use; and

Whereas, The FDA did not gain regulatory power over e-cigarettes until 2016, so many popular brands that launched before that date, including market leader Juul, are currently available for sale despite lacking explicit FDA authorization. The agency has given manufacturers until May 2020 to retroactively apply for authorization; if at that point they cannot prove their products are "appropriate for the protection of public health," they could be removed from the market; and

Whereas, The "precautionary principle," an increasingly accepted guideline for public health and environmental policy, states that "When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically; In this context the proponent of an activity, rather than the public, should bear the burden of proof"; and

Whereas, An increasing number of states (Michigan, New York, Massachusetts, Rhode Island) and municipalities (Los Angeles and San Francisco), among others, are filling a regulatory void caused by federal inaction and are banning sales of flavored tobacco and vaping products as research shows these are harmful, to health, addictive, and marketed towards youth; and

Whereas, Officials in San Francisco and other municipalities have proposed new regulations that would prohibit the sale of any e-cigarette that has not undergone FDA review; any e-cigarette that is required to have, but has not received, FDA pre-market review could not be sold at a store or bought online and shipped to a San Francisco address until the FDA completes its review and allows the products to be sold;" and

Whereas, This proposal is in line with both the precautionary principle and Hippocratic dictum, and is increasingly supported by research on the impacts and risks of vaping and electronic cigarettes; therefore be it

RESOLVED, That our American Medical Association support regulations that would prohibit the sale of any e-cigarette or other vaping product that has not undergone U.S. Food and Drug Administration (FDA) pre-market review until the FDA completes its review and allows the products to be sold. (New HOD Policy)

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

Received: 10/11/19

## RELEVANT AMA POLICY

### **Legal Action to Compel FDA to Regulate E-Cigarettes D-495.992**

Our AMA will consider joining other medical organizations in an amicus brief supporting the American Academy of Pediatrics legal action to compel the U.S. Food and Drug Administration to take timely action to establish effective regulation of e-cigarettes, cigars and other nicotine tobacco products.

Citation: Res. 432, A-18

### **Sales and Distribution of Tobacco Products and Electronic Nicotine Delivery Systems (ENDS) and E-cigarettes H-495.986**

H-495.986 Tobacco Product Sales and Distribution

Our AMA:

- (1) recognizes the use of e-cigarettes and vaping as an urgent public health epidemic and will actively work with the Food and Drug Administration and other relevant stakeholders to counteract the marketing and use of addictive e-cigarette and vaping devices, including but not limited to bans and strict restrictions on marketing to minors under the age of 21;
- (2) encourages the passage of laws, ordinances and regulations that would set the minimum age for purchasing tobacco products, including electronic nicotine delivery systems (ENDS) and e-cigarettes, at 21 years, and urges strict enforcement of laws prohibiting the sale of tobacco products to minors;
- (3) supports the development of model legislation regarding enforcement of laws restricting children's access to tobacco, including but not limited to attention to the following issues: (a) provision for licensure to sell tobacco and for the revocation thereof; (b) appropriate civil or criminal penalties (e.g., fines, prison terms, license revocation) to deter violation of laws restricting children's access to and possession of tobacco; (c) requirements for merchants to post notices warning minors against attempting to purchase tobacco and to obtain proof of age for would-be purchasers; (d) measures to facilitate enforcement; (e) banning out-of-package cigarette sales ("loosies"); and (f) requiring tobacco purchasers and vendors to be of legal smoking age;
- (4) requests that states adequately fund the enforcement of the laws related to tobacco sales to

minors;

(5) opposes the use of vending machines to distribute tobacco products and supports ordinances and legislation to ban the use of vending machines for distribution of tobacco products;

(6) seeks a ban on the production, distribution, and sale of candy products that depict or resemble tobacco products;

(7) opposes the distribution of free tobacco products by any means and supports the enactment of legislation prohibiting the disbursement of samples of tobacco and tobacco products by mail;

(8) (a) publicly commends (and so urges local medical societies) pharmacies and pharmacy owners who have chosen not to sell tobacco products, and asks its members to encourage patients to seek out and patronize pharmacies that do not sell tobacco products; (b) encourages other pharmacists and pharmacy owners individually and through their professional associations to remove such products from their stores; (c) urges the American Pharmacists Association, the National Association of Retail Druggists, and other pharmaceutical associations to adopt a position calling for their members to remove tobacco products from their stores; and (d) encourages state medical associations to develop lists of pharmacies that have voluntarily banned the sale of tobacco for distribution to their members; and

(9) opposes the sale of tobacco at any facility where health services are provided; and

(10) supports that the sale of tobacco products be restricted to tobacco specialty stores.

Citation: CSA Rep. 3, A-04; Appended: Res. 413, A-04; Reaffirmation A-07; Amended: Res. 817, I-07; Reaffirmation A-08; Reaffirmation I-08; Reaffirmation A-09; Reaffirmation I-13; Reaffirmation A-14; Reaffirmation I-14; Reaffirmation A-15; Modified in lieu of Res. 421, A-15; Modified in lieu of Res. 424, A-15; Reaffirmation I-16; Appended: Res. 926, I-18

### **Electronic Cigarettes, Vaping, and Health H-495.972**

1. Our AMA urges physicians to: (a) educate themselves about electronic nicotine delivery systems (ENDS), including e-cigarettes, be prepared to counsel patients about the use of these products and the potential for nicotine addiction and the potential hazards of dual use with conventional cigarettes, and be sensitive to the possibility that when patients ask about e-cigarettes, they may be asking for help to quit smoking; (b) consider expanding clinical interviews to inquire about "vaping" or the use of e-cigarettes; (c) promote the use of FDA-approved smoking cessation tools and resources for their patients and caregivers; and (d) advise patients who use e-cigarettes to take measures to assure the safety of children in the home who could be exposed to risks of nicotine overdose via ingestion of replacement e-cigarette liquid that is capped or stored improperly.

2. Our AMA: (a) encourages further clinical and epidemiological research on e-cigarettes; (b) supports education of the public on the health effects, including toxins and carcinogens of electronic nicotine delivery systems (ENDS) including e-cigarettes; and (c) recognizes that the use of products containing nicotine in any form among youth, including e-cigarettes, is unsafe and can cause addiction.

3. Our AMA supports legislation and associated initiatives and will work in coordination with the Surgeon General to prevent e-cigarettes from reaching youth and young adults through various means, including, but not limited to, CDC research, education and a campaign for preventing and reducing use by youth, young adults and others of e-cigarettes, and combustible and emerging tobacco products.

Citation: CSAPH Rep. 2, I-14; Modified in lieu of Res. 412, A-15; Modified in lieu of Res. 419, A-15; Reaffirmed: Res. 421, A-15; Modified: CSAPH Rep. 05, A-18; Reaffirmed: CSAPH Rep. 03, A-19; Appended: Res. 428, A-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 927  
(I-19)

Introduced by: Washington, Hawaii  
Subject: Climate Change  
Referred to: Reference Committee K

Whereas, Climate change could have a devastating effect on human and environmental health, including higher rates of respiratory and heat-related illness, increased prevalence of vector-borne and waterborne diseases, food and water insecurity, and malnutrition; and

Whereas, Persons who are elderly, sick, or poor are especially vulnerable to these potential consequences; and

Whereas, Addressing climate change could have substantial benefits to human health and avert dire environmental outcomes; and

Whereas, Our AMA and its physicians can play a role in achieving that goal; therefore be it

RESOLVED, That our American Medical Association acknowledge that:

1. Climate change is a critical public health issue.
2. Potential effects of climate change on human health include higher rates of respiratory and heat-related illness, increased prevalence of vector-borne and waterborne diseases, food and water insecurity, and malnutrition. Persons who are elderly, sick, or poor are especially vulnerable to these potential consequences.
3. We support educating the medical community on the potential adverse public health effects of global climate change and incorporating the health implications of climate change into the spectrum of medical education, including topics such as population displacement, heat waves and drought, flooding, infectious and vector-borne diseases, and potable water supplies.
4. We recognize the importance of physician involvement in policymaking at the state, national, and global level and support efforts to search for novel, comprehensive, and economically sensitive approaches to mitigating climate change to protect the health of the public; and recognize that whatever the etiology of global climate change, policymakers should work to reduce human contributions to such changes.
5. We encourage physicians to adopt programs for environmental sustainability in their practices, share these concepts with their patients and their communities. and to serve as role models for promoting environmental sustainability.
6. We encourage physicians to work with local and state health departments to strengthen the public health infrastructure to ensure that the global health effects of climate change can be anticipated and responded to more efficiently.
7. We support epidemiological, translational, clinical and basic science research necessary for evidence-based global climate change policy decisions related to health care and treatment. (New HOD Policy)

Fiscal Note: Minimal - less than \$1,000  
Received: 10/16/19



## **RELEVANT AMA POLICY**

### **AMA Advocacy for Environmental Sustainability and Climate H-135.923**

Our AMA (1) supports initiatives to promote environmental sustainability and other efforts to halt global climate change; (2) will incorporate principles of environmental sustainability within its business operations; and (3) supports physicians in adopting programs for environmental sustainability in their practices and help physicians to share these concepts with their patients and with their communities.

Citation: Res. 924, I-16

### **Global Climate Change and Human Health H-135.938**

Our AMA:

1. Supports the findings of the Intergovernmental Panel on Climate Change's fourth assessment report and concurs with the scientific consensus that the Earth is undergoing adverse global climate change and that anthropogenic contributions are significant. These climate changes will create conditions that affect public health, with disproportionate impacts on vulnerable populations, including children, the elderly, and the poor.
2. Supports educating the medical community on the potential adverse public health effects of global climate change and incorporating the health implications of climate change into the spectrum of medical education, including topics such as population displacement, heat waves and drought, flooding, infectious and vector-borne diseases, and potable water supplies.
3. (a) Recognizes the importance of physician involvement in policymaking at the state, national, and global level and supports efforts to search for novel, comprehensive, and economically sensitive approaches to mitigating climate change to protect the health of the public; and (b) recognizes that whatever the etiology of global climate change, policymakers should work to reduce human contributions to such changes.
4. Encourages physicians to assist in educating patients and the public on environmentally sustainable practices, and to serve as role models for promoting environmental sustainability.
5. Encourages physicians to work with local and state health departments to strengthen the public health infrastructure to ensure that the global health effects of climate change can be anticipated and responded to more efficiently, and that the AMA's Center for Public Health Preparedness and Disaster Response assist in this effort.
6. Supports epidemiological, translational, clinical and basic science research necessary for evidence-based global climate change policy decisions related to health care and treatment.

Citation: CSAPH Rep. 3, I-08; Reaffirmation A-14; Reaffirmed: CSAPH Rep. 04, A-19

### **AMA to Protect Human Health from the Effects of Climate Change by Ending its Investments in Fossil Fuel Companies D-135.969**

Our AMA, AMA Foundation, and any affiliated corporations will work in a timely, incremental, and fiscally responsible manner, to the extent allowed by their legal and fiduciary duties, to end all financial investments or relationships (divestment) with companies that generate the majority of their income from the exploration for, production of, transportation of, or sale of fossil fuels.

Citation: BOT Rep. 34, A-18

**Stewardship of the Environment H-135.973**

The AMA: (1) encourages physicians to be spokespersons for environmental stewardship, including the discussion of these issues when appropriate with patients; (2) encourages the medical community to cooperate in reducing or recycling waste; (3) encourages physicians and the rest of the medical community to dispose of its medical waste in a safe and properly prescribed manner; (4) supports enhancing the role of physicians and other scientists in environmental education; (5) endorses legislation such as the National Environmental Education Act to increase public understanding of environmental degradation and its prevention; (6) encourages research efforts at ascertaining the physiological and psychological effects of abrupt as well as chronic environmental changes; (7) encourages international exchange of information relating to environmental degradation and the adverse human health effects resulting from environmental degradation; (8) encourages and helps support physicians who participate actively in international planning and development conventions associated with improving the environment; (9) encourages educational programs for worldwide family planning and control of population growth; (10) encourages research and development programs for safer, more effective, and less expensive means of preventing unwanted pregnancy; (11) encourages programs to prevent or reduce the human and environmental health impact from global climate change and environmental degradation. (12) encourages economic development programs for all nations that will be sustainable and yet nondestructive to the environment; (13) encourages physicians and environmental scientists in the United States to continue to incorporate concerns for human health into current environmental research and public policy initiatives; (14) encourages physician educators in medical schools, residency programs, and continuing medical education sessions to devote more attention to environmental health issues; (15) will strengthen its liaison with appropriate environmental health agencies, including the National Institute of Environmental Health Sciences (NIEHS); (16) encourages expanded funding for environmental research by the federal government; and (17) encourages family planning through national and international support.

Citation: CSA Rep. G, I-89; Amended: CLRPD Rep. D, I-92; Amended: CSA Rep. 8, A-03; Reaffirmed in lieu of Res. 417, A-04; Reaffirmed in lieu of Res. 402, A-10; Reaffirmation I-16

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 928  
(I-19)

Introduced by: American Society of Clinical Oncology

Subject: CBD Oil and Supplement Use in Treatment

Referred to: Reference Committee K

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Whereas, Cannabidiol (CBD) oil has been rising in popularity around the country; and

Whereas, According to ASCO's 2018 National Cancer Opinion Survey, which tracks the U.S public's views on cancer research and care, nearly four in ten Americans believe cancer can be cured through alternative therapies<sup>1</sup>; and

Whereas, This news comes despite evidence that patients who use alternative therapies instead of standard cancer treatments have much higher mortality rates; and

Whereas, The studies around CBD oil and other supplements relieving cancer symptoms or cancer treatment side effects have been mixed and unstandardized<sup>3</sup>; and

Whereas, To date the Food and Drug Administration has not approved any CBD products to treat cancer or symptoms and side effects associated with care; and

Whereas, The FDA has issued a warning letter to at least one company for illegally selling unapproved products containing CBD with unsubstantiated claims that the products treat cancer and other diseases or conditions<sup>4</sup>; and

Whereas, More research is needed to evaluate not only the effectiveness of CBD oil and other supplements for cancer patients, but also the side effects and interactions with other, prescribed medications<sup>5,6</sup>; and

Whereas, According to a survey by the Arthritis Foundation, 79% of respondents are currently using CBD, have used it in the past, or are considering using it, with 87% of those who are currently using it saying it's to manage their arthritis symptoms<sup>2</sup>; and

Whereas, The Arthritis Foundation has issued recommendations warning users of the potential risks associated with CBD and advising them to consult with their physician<sup>7</sup>; therefore be it

RESOLVED, That our American Medical Association actively support and promote private and publicly funded research to support future evidence-based policymaking on Cannabidiol (CBD) products. (Directive to Take Action)

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

Received: 10/17/19

- 1 American Society of Clinical Oncology (ASCO). National Cancer Opinion Survey. 2018. <https://www.asco.org/sites/new-www.asco.org/files/content-files/research-and-progress/documents/2018-NCOS-Results.pdf> (Accessed September 24, 2019).
- 2 Arthritis Foundation. Patients Tell Us About CBD Use. 2019. <http://blog.arthritis.org/news/patients-tell-us-cbd-use/> (Accessed October 8, 2019).
- 3 The University of Texas MD Anderson Cancer Center. CBD oil and cancer: 9 things to know. 2019. <https://www.mdanderson.org/publications/cancerwise/cbd-oil-and-cancer--9-things-to-know.h00-159306201.html> (Accessed September 24, 2019).
- 4 The Food and Drug Administration. FDA warns company marketing unapproved cannabidiol products with unsubstantiated claims to treat cancer, Alzheimer's disease, opioid withdrawal, pain and pet anxiety. 2019. [https://www.fda.gov/news-events/press-announcements/fda-warns-company-marketing-unapproved-cannabidiol-products-unsubstantiated-claims-treat-cancer?utm\\_campaign=072319\\_PR\\_FDA%20warns%20firm%20selling%20cannabidiol%20products%20with%20unproven%20claims&utm\\_medium=email&utm\\_source=Eloqua](https://www.fda.gov/news-events/press-announcements/fda-warns-company-marketing-unapproved-cannabidiol-products-unsubstantiated-claims-treat-cancer?utm_campaign=072319_PR_FDA%20warns%20firm%20selling%20cannabidiol%20products%20with%20unproven%20claims&utm_medium=email&utm_source=Eloqua) (Accessed September 24, 2019).
- 5 Stout, S. M., & Cimino, N. M. (2014). Exogenous cannabinoids as substrates, inhibitors, and inducers of human drug metabolizing enzymes: a systematic review. *Drug metabolism reviews*, 46(1), 86-95.
- 6 Qian, Y., Gurley, B. J., & Markowitz, J. S. (2019). The Potential for Pharmacokinetic Interactions Between Cannabis Products and Conventional Medications. *Journal of clinical psychopharmacology*, 39(5), 462-471.
- 7 Arthritis Foundation. Arthritis Foundation CBD Guidance for Adults with Arthritis. 2019. <https://www.arthritis.org/living-with-arthritis/pain-management/chronic-pain/arthritis-foundation-cbd-guidance-for-adults.php> (Accessed October 8, 2019).

## AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 929  
(I-19)

Introduced by: American Association of Public Health Physicians

Subject: Regulating Marketing and Distribution of Tobacco Products and Vaping-Related Products

Referred to: Reference Committee K

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1 Whereas, The 2019 outbreak of “E-cigarette and Vapor Associated Pulmonary Illness” (EVAPI)  
2 has so far been almost entirely associated with the use of illicit, illegal, and/or user-modified  
3 “electronic cigarette” products, especially those containing THC; and  
4

5 Whereas, Nicotine is highly addictive; and  
6

7 Whereas, It is important to decrease the rates of nicotine use and dependence in all age  
8 groups, especially youth; and  
9

10 Whereas, It is important to decrease the morbidity and mortality from nicotine products by all  
11 appropriate means; and  
12

13 Whereas, It is unclear whether prohibition of legal e-cigarette and “vaping” products would  
14 increase or decrease the use of illicit, illegal, and/or user-modified products; and  
15

16 Whereas, The net effect of e-cigarette flavoring bans on adult smokers is unclear; and  
17

18 Whereas, There is an urgent need to decrease the addictiveness of electronic nicotine delivery  
19 systems (ENDS); therefore be it

1 RESOLVED, That our American Medical Association support strict marketing standards to  
2 prevent all nicotine-related products from being marketed to, or attractive to, children,  
3 adolescents, and young adults, including but not limited to the following measures:

- 4
- 5 • Banning print advertising except in adult-only publications or media (adults are >85% of
- 6 audience).
- 7 • Banning advertising and/or sponsorship at stadiums, concerts, sporting or other public
- 8 events that are not primarily targeted to adults.
- 9 • Banning offers of any school or college scholarships by any company selling tobacco
- 10 products.
- 11 • Banning television advertising of any tobacco products, including any vapor products.
- 12 • Banning advertising, marketing and sale of tobacco products that:
  - 13 – Uses the terms "candy" or "candies" or variants in spelling, such as "kandy" or
  - 14 "kandeez," "bubble gum," "cotton candy," and "gummi bear", and "milkshake."
  - 15 – Uses the terms "cake" or "cakes" or variants such as "cupcake."
  - 16 – Uses packaging, trade dress or trademarks that imitate those of food or other products
  - 17 primarily targeted to minors such as candy, cookies, juice boxes or soft drinks.
  - 18 – Uses packaging that contains images of food products primarily targeted to minors such
  - 19 as juice boxes, soft drinks, soda pop, cereal, candy, or desserts.
  - 20 – Imitates a consumer product designed or intended primarily for minors
  - 21 – Uses cartoons or cartoon characters.
  - 22 – Uses images or references to superheroes.
  - 23 – Uses any likeness to images, characters, or phrases that are known to appeal primarily
  - 24 to minors, such as "unicorn".
  - 25 – Uses a video game, movie, video, or animated television show known to appeal
  - 26 primarily to minors.
- 27 • Banning advertising and marketing of tobacco products, including vapor products, that:
  - 28 – Does not accurately represent the ingredients contained in the products.
  - 29 – Uses contracted spokespeople or individuals that do not appear to be at least 25 years
  - 30 of age.
- 31 • Banning advertising on outdoor billboards near schools and playgrounds.
- 32 • Requiring labels to include warnings protecting youth such as "Sales to Minors Prohibited"
- 33 or "Underage Sales Prohibited" and/or "Keep Out of Reach of Children".
- 34 • Requiring all advertising to be accurate and not misleading (New HOD Policy); and be it
- 35 further

36

37 RESOLVED, That our AMA support the use of the most up-to-date and effective technology for  
38 verifying the age of would-be purchasers of tobacco products and vaping-related products, both  
39 online and in bricks-and-mortar retail outlets (New HOD Policy); and be it further

40

41 RESOLVED, That our AMA oppose sales of tobacco products or vaping-related products on any  
42 third-party marketplace such as Alibaba, Amazon, eBay, et al, where the third-party marketplace  
43 does not take full responsibility for verifying age; blocking unregulated cannabis and THC  
44 products; identifying and prohibiting all counterfeit products; and forbidding packaging and other  
45 materials that allow illicit sales of any tobacco product (New HOD Policy); and be it further

46

47 RESOLVED, That our AMA support licensing and frequent inspections of all retail outlets selling  
48 any tobacco products or vaping-related products, with loss of license for repeated violations  
49 (e.g., three violations in a three year period) (New HOD Policy); and be it further

1 RESOLVED, That our AMA support limitations on the concentration, chemical form, and vehicle  
2 chemistry of all nicotine-related products, with special attention to the European product  
3 standards which seem to lead to much lower addictiveness than many of the ENDS products  
4 sold in the USA (New HOD Policy); and be it further  
5

6 RESOLVED, That our AMA support a ban on all self-service displays of tobacco products,  
7 which would require all tobacco products and vaping-related products to be behind a counter or  
8 in a locked display and accessible only to a store employee (New HOD Policy); and be it further  
9

10 RESOLVED, That our AMA support a ban on sales of all tobacco products and vaping-related  
11 products except in stores that display signage indicating that (a) "Unaccompanied Minors Are  
12 Not Allowed on Premises" or (b) "Products are Not for Sale to Minors" or (c) "Underage Sale  
13 Prohibited", and that enforce these rules consistently (New HOD Policy); and be it further  
14

15 RESOLVED, That our AMA support a ban on "straw man" sellers, which would make it illegal for  
16 any person who is not a licensed tobacco product dealer or vaping-related product dealer to  
17 sell, barter for, or exchange any tobacco product or vaping-related products (New HOD Policy);  
18 and be it further  
19

20 RESOLVED, That our AMA support legislation that would discourage "straw man" distribution by  
21 prohibiting the retail sale of quantities likely intended for more than one consumer, such as the  
22 retail sale to one customer of (a) more than two electronic-cigarette or vape devices; (b) more  
23 than five standard packages of e-liquids; (c) more than 20 packs of cigarettes; or (d) similarly  
24 determined quantities of other tobacco products and/or vaping-related products. (New HOD  
25 Policy)

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

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