

## Reference Committee E

### CSAPH Report(s)

04 Pharmacovigilance

### Resolution(s)

- 501 Ensuring Continued Access to Equitable Take-Home Methadone Treatment
- 502 Advocating for Heat Exposure Protections for Outdoor Workers
- 503 Marketing Guardrails for the "Over-Medicalization" of Cannabis Use
- 504 Air Pollution and COVID: A Call to Tighten Regulatory Standards
- 505 Representation of Dermatological Pathologies in Varying Skin Tones
- 506 Enhancing Harm Reduction for People Who Use Drugs

REPORT 4 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (November 2021)  
Pharmacovigilance  
(Res 518-A-19, Chemical Variability in Pharmaceutical Products)  
(Reference Committee E)

EXECUTIVE SUMMARY

Objective. In past AMA House of Delegates meeting, confusion about several concepts detailed in the multiple resolutions related to the quality of pharmaceutical products and concepts related to pharmacovigilance (PV) in general was recognized. Your Council on Science and Public Health (CSAPH) noted that there are several issues related to PV, track and trace, and testing and verification of pharmaceuticals that could benefit from further study, in addition to addressing referred Resolution 518-A-19, Chemical Variability in Pharmaceutical Products.

Methods. English-language articles were selected from a search of the PubMed database through August 2021 using the search terms “pharmacovigilance,” “pharmaceutical/drug quality,” and “pharmaceutical/drug impurities.” Additional articles were identified from a review of the references cited in retrieved publications. Searches of selected medical specialty society and international, national, and local government agency websites were conducted to identify clinical guidelines, position statements, and reports.

Results. The originally referred resolution that initiated this report was in response to the recalls of multiple drug products because of impurities present in the medications. These impurities were identified by the FDA and partner testing. The FDA subsequently informed the public about the problem, continues to investigate the issue, and continues to take corrective action. The source of detected impurities is linked to manufacturing issues and subsequent inspections revealed systemic problems of supervision that could have created the conditions for quality issues to arise; corrective action is underway. Importantly, FDA procedures identified the issue.

Conclusion. PV is a continuous process requiring active participation and combined efforts from physicians, other authorized prescribers, the pharmaceutical industry, government regulators, public health officials, clinicians, and health care organizations. Informed participation by all in PV processes is necessary to continually improve drug product safety, drug supply chain integrity and to identify safety signals. The AMA already has significant, relevant, and well-written policy related to PV and drug quality. Therefore, your Council recommends updating two outdated policies and reaffirmation of several existing polices.

# REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 4-N-21

Subject: Pharmacovigilance  
(Res 518-A-19, Chemical Variability in Pharmaceutical Products)

Presented by: Alexander Ding, MD, MS, MBA, Chair

Referred to: Reference Committee E

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## 1 INTRODUCTION

2

3 Resolution 518-A-19, “Chemical Variability in Pharmaceutical Products,” introduced by the  
4 American College of Cardiology and referred by the House of Delegates (HOD) asked:

5

6 That our American Medical Association (AMA) do a study and report back by the 2019  
7 Interim Meeting regarding the pharmaceutical variability, both in active pharmaceutical  
8 ingredient and dissolution, the impact on patient care and make recommendations for action  
9 from their report findings; that our AMA advocate for legislation requiring independent testing  
10 and verification of the chemical content of batches of pharmaceuticals; and that our AMA  
11 advocate for the logging of batches at the patient level, so the batches can be traced and  
12 connected to patient outcomes or adverse events.

13

14 In addition, two resolutions were introduced and debated at I-19 on the topic of pharmaceutical  
15 production and quality. At both A-19 and I-19, there was confusion about several concepts detailed  
16 in the resolutions and the concept of pharmacovigilance (PV) in general. Your Council on Science  
17 and Public Health (CSAPH) noted that there are several issues related to PV, track and trace, and  
18 testing and verification of pharmaceuticals that could benefit from further study. This report  
19 summarizes and explains the current state of PV for medications taken by patients in the United  
20 States; describes the role of the U.S. Food and Drug Administration (FDA) in PV; explains Drug  
21 Supply Chain and Security Act (DSCSA, also called “track and trace”) and its implementation;  
22 clarifies testing and verification procedures for medications; comments on issues associated with  
23 the pharmaceutical supply chain related to medication safety and quality; and provides  
24 recommendations related to PV policy. Additionally, CSAPH acknowledges the delay in this report  
25 due to the COVID-19 public health emergency and shifting of priorities for Council staff. This  
26 report from the Council also includes new developments related to pharmaceutical quality that have  
27 arisen during the COVID-19 public health emergency.

28

## 29 METHODS

30

31 English-language articles were selected from a search of the PubMed database through August  
32 2021 using the search terms “pharmacovigilance,” “pharmaceutical/drug quality,” and  
33 “pharmaceutical/drug impurities.” Additional articles were identified from a review of the  
34 references cited in retrieved publications. Searches of selected medical specialty society and  
35 international, national, and local government agency websites were conducted to identify clinical  
36 guidelines, position statements, and reports.

## 1 BACKGROUND

2  
3 PV is defined by the World Health Organization (WHO) as comprising the science and activities  
4 relating to the detection, assessment, understanding, and prevention of adverse effects and other  
5 drug-related problems.<sup>1</sup> PV is described as a systematic process involving the collection of  
6 information about the nature, severity, clinical characteristics, and outcomes of adverse effects of  
7 medicinal products; documentation and analysis of the collected adverse-effects data to detect a  
8 causal link between the medicinal product and adverse effect; remedial actions to eliminate (or  
9 minimize) hazards posed by adverse effects of medicinal products, and continued monitoring of the  
10 impact of any such remedial actions.<sup>2</sup> The field of PV has undergone rapid growth over the last two  
11 decades.<sup>3</sup>

12  
13 Various medicinal product-related safety issues not attributable to the pharmacologic properties of  
14 the product are also a part of PV. Safety issues include dosage form problems such as  
15 contamination, physical defects, abnormal odor or taste; product packaging issues such as broken  
16 seals, leaking bottles, and incorrect fill amount; labeling problems such as missing labels, missing  
17 lot numbers, and missing expiration dates; and counterfeit medicines. Upon learning about issues,  
18 regulatory authorities ask manufacturers to take remedial actions, for example, product recalls. This  
19 report addresses many aspects of adverse events and the tracking of those, but also drug product  
20 supply chains and recent and ongoing efforts to improve the tracking of medicinal product  
21 production, distribution, shipping, and location.

### 22 *Terminology*

23  
24  
25 PV is a growing field and mounting concern in healthcare, which aims to enhance patient care and  
26 patient safety in relation to the use of medicines. However, often in healthcare, the terms including  
27 adverse event, adverse drug reaction, and side effect are used interchangeably. Experts note that  
28 standardization of medication-safety-related terminology is an important goal of PV. With that in  
29 mind, the following terms are provided for clarity:<sup>4,5</sup>

30  
31 Adverse event (AE). All undesirable events occurring after the use of a medicinal product that may  
32 not necessarily be ascribed to the product are AEs.

33  
34 Adverse drug reaction (ADR). A response to a drug which is noxious and unintended, and which  
35 occurs at doses normally used for the prophylaxis, diagnosis, or therapy of disease, or used for  
36 modifications of physiological function, is an ADR.

37  
38 AEs or ADRs are considered unexpected if it is not consistent with applicable product information  
39 or characteristics of the drug. Serious AEs or ADRs are untoward medical occurrences that at any  
40 dose results in death, are life-threatening, requires inpatient hospitalization or prolongation of  
41 existing hospitalization, and/or results in persistent of significant disability or incapacity.

42  
43 Side effect. An unintended effect, regardless of dosage, that occurs related to the pharmacological  
44 properties of a medication, is considered a side effect; side effects are not necessarily adverse and  
45 are often foreseen.

## 46 PHARMACOVIGILANCE AT THE U.S. FOOD AND DRUG ADMINISTRATION (FDA)

47  
48  
49 The FDA has several offices dedicated to drug quality, surveillance, and epidemiology. The aim of  
50 FDA PV processes is to collect information about various broad aspects of medicinal product  
51 safety. These aspects are listed in the FDA's guidance document on good PV practices.<sup>6</sup>

1 Specifically, the document provides guidance on safety signal identification,  
2 pharmacoepidemiologic assessment and safety signal interpretation, and PV plan development. The  
3 FDA also hosts an informational website that provides and outlines resources related to  
4 pharmaceutical quality.<sup>7</sup>

5  
6 *FDA Office of Surveillance and Epidemiology (OSE)*

7  
8 The FDA's Office of Surveillance and Epidemiology (OSE) monitors and evaluates the safety  
9 profiles of drugs using a variety of tools and disciplines throughout the life cycle of the drugs.<sup>8</sup>  
10 OSE has four core functions: pharmacovigilance; pharmacoepidemiology; medication error  
11 prevention and analysis; and risk management. The Office operates across multiple disciplines to  
12 review and assess the safety of medicines and maintains a system of postmarketing surveillance  
13 and risk assessment programs to identify adverse events that did not appear during the drug  
14 development process. OSE evaluates more than 1.5 million adverse event reports (AERs)  
15 submitted every year to the FDA's MedWatch program,<sup>9</sup> part of the FDA Adverse Event Reporting  
16 System (FAERS)<sup>10,11</sup> or Safety Reporting Portal (SRP).<sup>12</sup>

17  
18 OSE is part of the Center for Drug Evaluation and Research (CDER) and houses the Office of  
19 Pharmacovigilance and Epidemiology (OPE) as well as the Office of Medication Error Prevention  
20 and Risk Management. OPE's Division of PV (DPV) evaluates the safety of drug and therapeutic  
21 biologic products, engages in monitoring/surveillance, analyzes safety signals, recommends  
22 regulatory actions, and communicates relevant safety information. OPE and DPV recognize that  
23 pre-approval clinical trials of drugs have limitations and that the pharmaceutical industry and the  
24 FDA must rely on postmarket surveillance and AE reports to monitor medications and monitor for  
25 safety signals. OSE and its office and divisions are responsible for:

- 26
- 27 • Postmarketing safety surveillance for all marketed drug and therapeutic biologic products;
  - 28 • Conducting active drug safety surveillance;
  - 29 • Reviewing drug safety-related epidemiologic study protocols and study reports;
  - 30 • Ensuring that the postmarketing requirements conducted by sponsors meet the best  
31 practices in epidemiology and can provide robust and actionable evidence to inform  
32 regulatory decision making following initial approval;
  - 33 • Procuring, managing, and analyzing pharmaceutical sales and health care data to describe  
34 and characterize drug utilization levels and treatment patterns in the United States;
  - 35 • Working with drug companies to reduce medication errors related to confusing labels,  
36 labeling, drug packaging, and drug names that look alike or sound alike; and
  - 37 • Providing risk management expertise on development and implementation of programs and  
38 initiatives to support policies related to Risk Evaluation and Mitigation Strategies (REMS).
- 39

40 In May 2021, OSE issued its first annual report highlighting the key OSE initiatives to detect,  
41 assess, prevent, and monitor the risks of medicines, with a special focus on its efforts to respond to  
42 the COVID-19 pandemic.<sup>13</sup>

43  
44 *FDA Office of Pharmaceutical Quality (OPQ)*

45  
46 FDA's CDER also houses the Office of Pharmaceutical Quality (OPQ) which works to assure that  
47 quality medicines are available for the American public.<sup>14</sup> OPQ integrates assessment, inspection,  
48 surveillance, policy, and research activities to strengthen pharmaceutical quality on a global scale.  
49 OPQ oversees the quality of marketed drugs over the entire drug lifecycle and monitors the state of  
50 quality for all regulated manufacturing sites and drug products by establishing quality standards,  
51 including current good manufacturing practices (cGMP); identifying quality problems which

1 require corrective action; and encouraging the adoption of emerging technologies to enhance  
2 pharmaceutical quality. OPQ works closely with other FDA offices if enforcement decisions need  
3 to be made and strives to balance potential quality risks with the risk of a patient not getting a  
4 needed medication. It also attempts to anticipate quality problems before they develop so as to help  
5 prevent drug shortages.

6  
7 The OPQ 2019 annual report described activities in 2019 and over the office's five-year life,  
8 including efforts in drug assessment, inspection, surveillance, policy, and research. The report also  
9 detailed the number of additional FDA staff hired to work on pharmaceutical quality.<sup>15</sup> The 2020  
10 annual report on the state of pharmaceutical quality contains select quality indicators and trends  
11 that provide insight into the quality of the U.S. drug supply chain and includes an analysis of the  
12 impact of the COVID-19 public health emergency on the pharmaceutical supply chain and on the  
13 quality of drugs.<sup>16</sup>

#### 14 15 *Facility Inspections*

16  
17 A U.S. Government Accountability Office (GAO) report from December 2019, *Preliminary*  
18 *Findings Indicate Persistent Challenges with FDA Foreign Inspections*, noted that more than 60  
19 percent of drug manufacturers for the United States market are located overseas. The FDA inspects  
20 foreign and domestic drug manufacturers to ensure drug safety and effectiveness; however, the  
21 number of inspections of foreign drug manufacturers has declined since FY 2016 and most foreign  
22 inspections are preannounced. The report notes concerns about FDA's ability to oversee the global  
23 supply chain.<sup>17</sup>

24  
25 In March 2020, at the beginning of the COVID-19 public health emergency, the FDA made the  
26 decision to pause most foreign and domestic facility inspections, with the exception of mission-  
27 critical inspection work. This decision was made in response to federal guidelines to mitigate the  
28 spread of the COVID-19 virus. The Agency relied on alternative tools such as inspection reports  
29 from foreign regulators, records requests, and product sampling to complement its oversight  
30 activities.

31  
32 The FDA acknowledges that the pandemic had an impact on inspection work in a report titled  
33 "Resiliency Roadmap for FDA Inspectional Oversight," which outlines the effect of the public  
34 health emergency on inspection activities and the detailed plan for inspections and operations  
35 moving forward. The report notes that a significant backlog of both domestic and international  
36 inspections that are likely to persist through much of the next calendar year.<sup>18</sup>

#### 37 38 *FDA Drug Quality Sampling and Testing Programs*

39  
40 FDA Drug Quality Sampling and Testing Programs help assure that only safe and effective drugs  
41 are sold.<sup>19</sup> The FDA tests drugs in FDA laboratories and through research contracts and grants.  
42 This includes active pharmaceutical ingredients (API) used to make the product and the finished  
43 drug product sold to consumers. FDA tests drugs using the same standards that are part of the drug  
44 approval process for identity, strength, purity, and bioavailability, which is also used to establish  
45 bioequivalence. Although some research has indicated batch-to-batch variability,<sup>20</sup> FDA offices  
46 and labs evaluate these issues and take corrective action as necessary, including recalls.<sup>21</sup>

#### 47 48 DRUG SUPPLY CHAIN

49  
50 Of note when discussing the topic of PV is overall pharmaceutical supply chain issues. Because of  
51 the way API are distributed in the supply chain, one source of contaminated API can impact

1 multiple products from multiple manufacturers. At times, because of a lack of transparency in the  
2 supply chain, it is difficult and time-consuming to determine all links in the supply chain.

3  
4 Recently, considerable attention has been focused on supply chain resilience. In 2021, the FDA  
5 published several guidance documents related to supply chain security,<sup>22</sup> the White House released  
6 a report on policies to support the creation of resilient supply chains,<sup>23,24</sup> and The Duke-Margolis  
7 Center for Health Policy and the COVID Collaborative released a new white paper on challenges  
8 and potential solutions for resilient drug supply chains that complements the White House report.<sup>25</sup>  
9 All of these publications include aspects of AMA policy regarding drug shortage including calls for  
10 increased transparency, global cooperation, resiliency and redundancy in manufacturing capability,  
11 and the creation of a quality rating system. While advanced manufacturing, including continuous  
12 manufacturing,<sup>26</sup> is an important component to drug quality, the specifics regarding implications  
13 and implementation of advanced manufacturing are outside of the scope of this report.

14  
15 Additionally, a recent report from the National Academies of Sciences, Engineering, and Medicine,  
16 *Stronger Food and Drug Regulatory Systems Abroad*, recommends strategies and a framework that  
17 regulatory agencies worldwide can adopt to support the availability of good quality, safe food and  
18 medicines globally and to identify areas of greatest risk. The report also recommends ways that  
19 U.S. government agencies, international development donors, and the WHO can strengthen the  
20 capacity of food and drug regulators, particularly those in low- and middle-income countries. Such  
21 investments should prioritize the expansion of WHO's approval and quality control processes for  
22 priority medicines and vaccines; the development of tools for rapidly screening food and drug  
23 quality; and improving the evaluation of how well regulatory agencies are performing.<sup>27</sup>

## 24 25 PHARMACEUTICAL IMPURITIES

26  
27 The FDA, the International Conference on Harmonization (ICH), and the United States  
28 Pharmacopeia (USP) define an impurity as "any component of a drug substance that is not the  
29 chemical entity defined as the drug substance and in addition, for a drug product, any component  
30 that is not a formulation ingredient."<sup>28-30</sup> Impurities in a drug substance (i.e., an API) or a drug  
31 product that can arise due to synthetic/manufacturing processes (process-related impurities [PRIs])  
32 and degradation (degradation-related impurities [DRIs]), or due to factors such as storage  
33 conditions, containers, excipients, or contamination. In addition, impurities can be categorized as  
34 identified or unidentified, volatile or nonvolatile, or organic or inorganic species. Figure 1 provides  
35 a flowchart that details the categories of impurities.<sup>31</sup>

### 36 37 *Nitrosamine Impurities*

38  
39 Unacceptable levels of nitrosamine impurities in some batches of the angiotensin II receptor  
40 blocker (ARB) valsartan were first detected in 2018. Subsequently, impurities were found in other  
41 ARBs, as well as unrelated drugs, including ranitidine, nizatidine, metformin, varenicline, rifampin  
42 and rifapentine.<sup>32-34</sup>

43  
44 Nitrosamines are a group of chemical compounds, some of which can pose a risk to patients and  
45 public health due to their mutagenic properties. They are well known to be present in foods, such as  
46 smoked or grilled meats and fish, and they are also present in mainstream and sidestream air from  
47 combusted tobacco in cigarettes, cigars and pipes. Nitrosamines or their precursors can also be  
48 present in a wide variety of manufactured and natural products. Nitrosamines generally are not  
49 intentionally added to foods or consumer products but are formed from constituents of the foods or  
50 products that are either naturally present or added during production. When they are metabolized,  
51 nitrosamines are converted to alkylating agents. Some of these are known to damage DNA and

1 have been linked to an increased risk of cancer if a patient is exposed to unacceptable levels of the  
2 impurity for an extended period of time.<sup>35</sup>

3  
4 FDA testing found the levels of the nitrosamine N-nitrosodimethylamine (NDMA) increased under  
5 normal storage conditions and increase in samples stored at higher temperatures. FDA testing also  
6 determined that levels of NDMA present in drugs is similar to levels a person is exposed to through  
7 consuming grilled meats. The Agency has established “interim limits” for three nitrosamine  
8 compounds: NDMA, NDEA and NMBA.<sup>36</sup> The FDA also noted that the identification of  
9 nitrosamine impurities in tested drug samples may not reflect an emerging regulatory problem, but  
10 is an evolution of scientific methods that are capable of detecting the impurities at significantly  
11 lower levels than in the past.<sup>37</sup>

12  
13 In numerous updates, the FDA notes that they continue to work with manufacturers to investigate  
14 the source of nitrosamines in drug products and whether they are at a level that may pose risks to  
15 human health. The FDA and manufacturers are testing samples of certain medications that may  
16 contain nitrosamines and will continue to take rapid and appropriate action when needed.<sup>36,38-40</sup>  
17 Additionally, the FDA held a public workshop on nitrosamine impurities to educate about  
18 nitrosamine chemistry and toxicology, on the finding of nitrosamines as impurities in drugs, data  
19 gaps and research needs to address uncertainties in nitrosamine safety assessment, and about how  
20 to prevent or minimize their presence in drugs, as well as to provide a forum for an open discussion  
21 of questions.<sup>41</sup>

22  
23 Manufacturers are held responsible for understanding their manufacturing processes and following  
24 cGMP, which includes identifying and preventing the presence of unacceptable impurities. This  
25 involves developing new predictive approaches, along with using suitable methods to detect and  
26 control these impurities as well as others that may arise when making changes to manufacturing  
27 processes. The FDA issued and then revised an immediately-in-effect Guidance for Industry on the  
28 *Control of Nitrosamine Impurities in Human Drugs* which describes steps manufacturers of active  
29 pharmaceutical ingredients and drug products should take to detect and prevent objectionable  
30 levels of nitrosamine impurities in pharmaceutical products. The Guidance also describes  
31 conditions that may introduce nitrosamine impurities. Material in the Guidance is consistent with  
32 recommendations from the ICH on the assessment and control of mutagenic impurities.<sup>42</sup> USP has  
33 also provided information on the topic and has developed a new general chapter to provide  
34 information useful for ensuring the appropriate control of nitrosamine impurities in drug substances  
35 which becomes official on Dec 1, 2021.<sup>43-45</sup>

## 36 37 POSTMARKET SURVEILLANCE

38  
39 The FDA outlines risk-based best practices for conducting ongoing postmarket safety surveillance  
40 activities for drugs and biological products in the document, “Best Practices in Drug and Biological  
41 Product Postmarket Safety Surveillance for FDA Staff,” which was required under a provision of  
42 the 21st Century Cures Act.<sup>46</sup> The document includes considerations that inform the frequency and  
43 extent of systematic drug and biologic safety monitoring; considerations based on specific product  
44 types and patient populations; safety signal identification based on screening and data mining of  
45 the FDA’s AE reporting system and other data sources, including general practices for the  
46 frequency and extent of screening these data sources, as well as prioritizing identified signals; a  
47 multidisciplinary, comprehensive evaluation of the identified safety signal that integrates the  
48 cumulative data gathered from all available sources; an assessment of the causal association  
49 between the identified AE and the product; and an overview of regulatory and other actions that  
50 can be taken in response to identified safety signals.



1 *Adverse Event Reporting*

2  
3 Regulatory authorities are interested in receiving reports of serious and unexpected AEs and ADRs  
4 on an urgent and priority basis.<sup>47</sup> All reporting by physicians is voluntary and also strongly  
5 recommended; the FDA gives extra credence to physician reports. The Safety Reporting Portal  
6 (SRP)<sup>12</sup> streamlines the process of reporting product safety issues to the FDA and the NIH,  
7 formerly done through FAERS<sup>10,11</sup> and MedWatch<sup>9</sup> Online Voluntary Reporting Form. The SRP  
8 can be used by manufacturers, health care professionals, researchers, public health officials, and  
9 patients.<sup>48</sup>

10  
11 DRUG SUPPLY CHAIN AND SECURITY ACT

12  
13 The Drug Supply Chain and Security Act (DSCSA) also called “track and trace,” enacted as part of  
14 the Drug Quality and Security Act of 2013, includes extensive requirements related to supply chain  
15 participants and regulated products. The law outlines the steps manufacturers, repackagers,  
16 wholesale distributors, dispensers (i.e., pharmacies), and third-party logistics providers need to take  
17 to develop an electronic, interoperable system that tracks a drug at the unit-level throughout the  
18 drug supply chain.<sup>49-51</sup> For the tracking component, each supply chain entity should be able to see a  
19 valid chain of custody for any product. The tracking component will allow FDA the ability to  
20 follow the chain of custody of a product back to its point of origin.

21  
22 DSCSA includes provisions on product identification and verification, data sharing, detection and  
23 response to suspect any illegitimate products, recordkeeping, and unified licensure standards for  
24 wholesale distributors and third-party logistics providers. The schedule of milestones has been  
25 broken down into three phases:

- 26  
27
- Phase 1: Lot-level traceability and verification of products and transactions (2015)
  - Phase 2: Drug product serialization and enhanced verification of serialized products (2017-  
28 2020)
  - Phase 3: Unit-level traceability (2023)
- 29  
30  
31

32 Requirements for Phase 1 are thus already in effect. In January 2015, the FDA expected dispensers  
33 to have established a system for verification and handling of suspect or illegitimate products, and to  
34 confirm that trading partners (i.e., manufacturers, wholesale distributors) are appropriately  
35 registered or licensed with the FDA or the appropriate state authority. As of March 2016, the FDA  
36 began enforcing the requirement. In addition, dispensers must maintain such information for no  
37 less than 6 years after the date of the transaction. Currently with a product transaction, the ability to  
38 track and trace the product down to the lot level is possible.

39  
40 By 2023, electronic package-level tracing information using a product identifier will be required. A  
41 recent presentation from FDA’s CDER provided updates on implementation of these security  
42 requirements for enhanced drug distribution security.<sup>52</sup> The stated goals are to implement  
43 interoperable, electronic tracing of products at the package level by 2023 that will enable secure  
44 tracing of products at the package level; use product identifiers to verify products at the package  
45 level; enable prompt response to suspect and illegitimate products when found; and improve  
46 efficiency of recalls. National standards for licensure for wholesale distributors and third-party  
47 logistics providers will be established by 2023 as well.

48  
49 Additionally, four guidance documents describing key details of how the FDA plans to secure the  
50 pharmaceutical supply chain were recently released. The documents relate to various aspects of the  
51 “track and trace” system.<sup>53</sup> *Enhanced Drug Distribution Security at the Package Level Under the*

1 *Drug Supply Chain Security Act* provides recommendations on the system attributes necessary for  
2 enabling the secure tracing of drug product at the package level, defined as the smallest individual  
3 salable unit of drug product for distribution by a manufacturer or repackager.<sup>54</sup> *Definitions of*  
4 *Suspect Product and Illegitimate Product for Verification Obligations Under the Drug Supply*  
5 *Chain Security Act Guidance for Industry* lays out the FDA’s current understanding of terms used  
6 to define “suspect” and “illegitimate” products.<sup>55</sup> *Product Identifiers under the Drug Supply Chain*  
7 *Security Act - Questions and Answers* clarifies information for industry.<sup>56</sup> *Drug Supply Chain*  
8 *Security Act Implementation: Identification of Suspect Product and Notification Guidance for*  
9 *Industry* is intended to aid certain trading partners in identifying a suspect product and specific  
10 scenarios that could significantly increase the risk of a suspect product entering the pharmaceutical  
11 distribution supply chain.<sup>57</sup>

### 12 13 CURRENT AMA POLICY

14  
15 AMA has several policies on the topic of PV (see appendix for full text). AMA Policy H-100.946,  
16 “Source and Quality of Medications Critical to National Health and Security,” supports studies of  
17 United States dependency on foreign components, legislative and regulatory initiatives to ensure  
18 proper domestic capacity, production, and quality of pharmaceuticals, and encourages the  
19 development and enforcement of standards that make the sources of pharmaceuticals and their  
20 chemical substrates used in the United States transparent to prescribers and the general public.  
21 Policy H-100.969, “Assuring the Safety and Quality of Foreign-Produced Pharmaceuticals,”  
22 addresses the safety and quality of foreign manufactured pharmaceuticals and supports inspection  
23 of all products entering the United States and surveillance inspections of foreign manufacturers.  
24 Policy D-100.977, “Pharmaceutical Quality Control for Foreign Medications,” advocates that the  
25 Congress and the FDA use their authorities to ensure safe imported drugs. Policy H-100.995,  
26 “Support of American Drug Industry,” supports pharmaceutical manufacturing industry efforts to  
27 develop and market pharmaceutical products meeting proper standards of safety and efficacy.  
28 Policy D-125.987, “Biosimilar Product Naming and Labeling,” supports appropriate PV for  
29 biosimilar products.

30  
31 Policies D-100.988, “Tracking and Punishing Distributors of Counterfeit Pharmaceuticals,”  
32 H-100.966, “Tracking and Punishing Distributors of Counterfeit Pharmaceuticals,” and D-100.985,  
33 “Federal Regulation and Computerized Tracking of Pharmaceuticals During Shipping and  
34 Handling from Manufacture Until Ultimately Received by Patient,” support pharmaceutical  
35 tracking systems, identification and eradication of illegal activities in the pharmaceutical industry  
36 and punishment of pharmaceutical counterfeiters. Policy H-120.958, “Supporting Safe Medical  
37 Products as a Priority Public Health Initiative,” supports reporting of adverse events; a coding  
38 system for prescription medicine packaging to improve patient safety; and the need for public  
39 health infrastructure and local consortiums to work on problems related to medical product safety.

40  
41 Policy H-100.956, “National Drug Shortages,” notes several relevant themes including: supporting  
42 the improvement of manufacturing quality systems; requiring drug manufacturers to establish a  
43 plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid  
44 production shortages whenever possible; urging the development of a comprehensive independent  
45 report on the root causes of drug shortages, which includes the number of manufacturers, economic  
46 factors and contracting practices; and urging the FDA to require manufacturers to provide greater  
47 transparency regarding production locations of drugs and to provide more detailed information  
48 regarding the causes and anticipated duration of drug shortages.

1 CONCLUSION

2  
3 The originally referred resolution that initiated this report was in response to the recalls of multiple  
4 drug products because of impurities present in the medications. These impurities were identified by  
5 the FDA and partner testing. The FDA subsequently informed the public about the problem,  
6 continues to investigate the issue, and continues to take corrective action. The source of detected  
7 impurities is linked to manufacturing issues and subsequent inspections revealed systemic  
8 problems of supervision that could have created the conditions for quality issues to arise; corrective  
9 action is underway. Importantly, FDA procedures identified the issue.

10  
11 PV is a continuous process requiring active participation and combined efforts from physicians,  
12 other authorized prescribers, the pharmaceutical industry, government regulators, public health  
13 officials, clinicians, and health care organizations. Informed participation by all in PV processes is  
14 necessary to continually improve drug product safety, maintain drug supply chain integrity, and to  
15 identify safety signals. The AMA already has significant, relevant, and well-written policy related  
16 to PV and drug quality. Therefore, your Council recommends updating two outdated policies and  
17 reaffirmation of several existing polices.

18  
19 RECOMMENDATIONS

20  
21 The Council on Science and Public Health recommends that the following be adopted in lieu of  
22 Resolution 518-A-19 and the remainder of the report be filed:

- 23  
24 1. That Policy D-100.988, "Tracking and Punishing Distributors of Counterfeit Pharmaceuticals"  
25 be amended by addition and deletion to read as follows:

26  
27 Our AMA will support the Food and Drug Administration's efforts to evaluate and facilitate  
28 implementation of effective tracking systems for pharmaceuticals, including all outlined  
29 implementation phases of the Drug Supply Chain and Security Act (DSCSA, Public Law 113-  
30 54) also called "track and trace," which contains extensive requirements and provisions related  
31 to supply chain participants and regulated products. (Modify Current HOD Policy)

- 32  
33 2. That Policy H-120.958, "Supporting Safe Medical Products as a Priority Public Health  
34 Initiative" be amended by addition and deletion to read as follows:

35  
36 Our AMA will: (1) work through the United States Adopted Names (USAN) Council to adopt  
37 methodology to help prevent "look alike-sound alike" errors in giving new drugs generic  
38 names;

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

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

44 (4) vigorously work to support the Drug Supply Chain and Security Act (DSCSA, Public Law  
45 113-54), including provisions on product identification and verification, data sharing, detection  
46 and response, and encourage efforts to create and expeditiously implement a national machine-  
47 readable coding system for prescription medicine packaging in an effort to improve patient  
48 safety;

49 (5) participate in and report on the work of the Healthy People ~~2010~~ 2030 initiative in the area  
50 of safe medical products especially as it relates to existing AMA policy; and

- 1 (6) seek opportunities to work collaboratively within the Medicine-Public Health initiative  
2 (H-440.991) and with the Food and Drug Administration (FDA), National Institutes of Health  
3 (NIH), United States Pharmacopoeia (USP) and Centers for Disease Control and Prevention  
4 (CDC) the Agency for ~~Health Care Policy and Research (AHCPR)~~ Healthcare Research and  
5 Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) to provide  
6 information to individual physicians and state medical societies on the need for public health  
7 infrastructure and local consortiums to work on problems related to medical product safety.  
8 (Modify Current HOD Policy)  
9
- 10 3. That Policy D-100.977, “Pharmaceutical Quality Control for Foreign Medications,” that calls  
11 upon Congress to provide the FDA with the necessary authority and resources to ensure that  
12 imported drugs are safe for American consumers and patients, be reaffirmed. (Reaffirm HOD  
13 Policy)  
14
- 15 4. That Policy D-100.985, “Federal Regulation and Computerized Tracking of Pharmaceuticals  
16 During Shipping and Handling from Manufacture Until Ultimately Received by Patient,”  
17 opposing illegal drug diversion, illegal Internet sales of drugs, illegal importation of drugs, and  
18 drug counterfeiting, be reaffirmed. (Reaffirm HOD Policy)  
19
- 20 5. That Policy D-100.988, “Tracking and Punishing Distributors of Counterfeit Pharmaceuticals,”  
21 supporting the FDA’s efforts to evaluate and facilitate implementation of effective tracking  
22 systems for pharmaceuticals, be reaffirmed. (Reaffirm HOD Policy)  
23
- 24 6. That Policy H-100.946, “Source and Quality of Medications Critical to National Health and  
25 Security,” supporting legislative and regulatory initiatives that help to ensure proper domestic  
26 capacity, production and quality of pharmaceutical and chemical substrates as a matter of  
27 public well-being and national security and encouraging the development and enforcement of  
28 standards that make the sources of pharmaceuticals and their chemical substrates used in the  
29 United States of America transparent to prescribers and the general public, be reaffirmed.  
30 (Reaffirm HOD Policy)  
31
- 32 7. That Policy H-100.969, “Assuring the Safety and Quality of Foreign-Produced  
33 Pharmaceuticals,” supporting the inspection of all foreign manufacturers of pharmaceutical  
34 chemicals and products which are exported to the United States to assure compliance with U.S.  
35 standards, be reaffirmed. (Reaffirm HOD Policy)  
36
- 37 8. That Policy H-100.995, “Support of American Drug Industry,” supporting the American  
38 pharmaceutical manufacturing industry in its efforts to develop and market pharmaceutical  
39 products meeting proper standards of safety and efficacy for the benefit of the American  
40 people, be reaffirmed. (Reaffirm HOD Policy)

Fiscal Note: Less than \$1000

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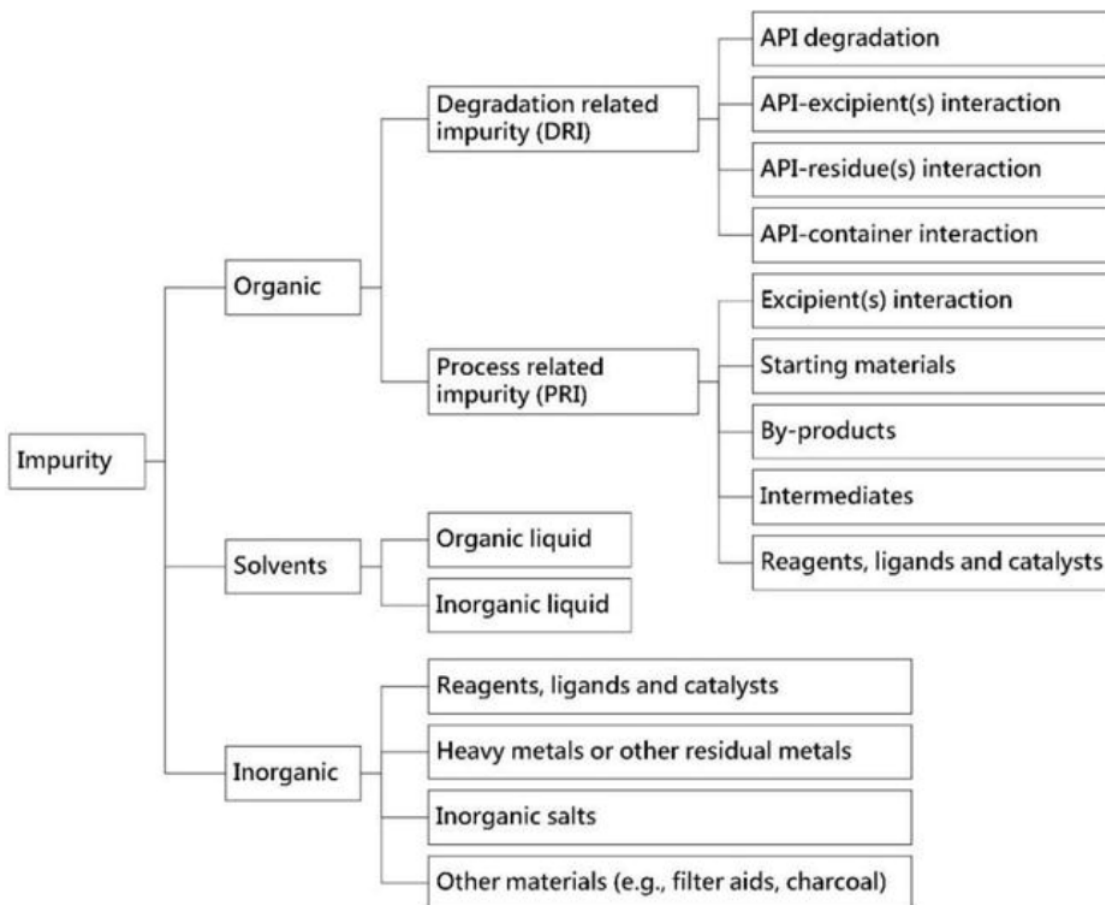
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**Figure 1.** Categorization of impurities from FDA and USP (figure from <sup>31</sup>).



## **APPENDIX: AMA Policies Related Pharmacovigilance**

### **D-100.977, “Pharmaceutical Quality Control for Foreign Medications”**

Our AMA will call upon Congress to provide the US Food and Drug Administration with the necessary authority and resources to ensure that imported drugs are safe for American consumers and patients. Res. 508, A-08

### **D-100.985, “Federal Regulation and Computerized Tracking of Pharmaceuticals During Shipping and Handling from Manufacture Until Ultimately Received by Patient”**

Our AMA will: (1) continue to actively oppose illegal drug diversion, illegal Internet sales of drugs, illegal importation of drugs, and drug counterfeiting; and (2) work with the Congress, the Food and Drug Administration, the Drug Enforcement Administration, and other federal agencies, the pharmaceutical industry, and other stakeholders to ensure that these illegal activities are minimized. Res. 501, A-04; Reaffirmation I-06; Reaffirmed: BOT Rep. 06, A-16; Reaffirmed: CMS Rep. 01, I-18

### **D-100.988, “Tracking and Punishing Distributors of Counterfeit Pharmaceuticals”**

Our AMA will support the Food and Drug Administration's efforts to evaluate and facilitate implementation of effective tracking systems for pharmaceuticals. Res. 924, I-03 Reaffirmation I-06 Reaffirmed: BOT Rep. 06, A-16

### **D-125.987, “Biosimilar Product Naming and Labeling”**

Our AMA urges the FDA to finalize Guidance on the naming and labeling conventions to be used for biosimilar products, including those that are deemed interchangeable. Any change in current nomenclature rules or standards should be informed by a better and more complete understanding of how such changes, including requiring a unique identifier for biologic USANs would impact prescriber attitudes and patient access, and affect post marketing surveillance. Actions that solely enhance product identification during surveillance but act as barriers to clinical uptake are counterproductive. However, because of unique product attributes, a relatively simple way to identify and track which biosimilar products have been dispensed to individual patients must be established. If unique identifiers for biosimilar USANs are required to support pharmacovigilance, they should be simple and the resulting names should reinforce similarities by using the same root name following standards for nonproprietary names established by the USAN Council. CSAPH Rep. 4, A-14

### **H-100.946, “Source and Quality of Medications Critical to National Health and Security”**

Our AMA: (1) supports studies that identify the extent to which the United States is dependent on foreign supplied pharmaceuticals and chemical substrates; (2) supports legislative and regulatory initiatives that help to ensure proper domestic capacity, production and quality of pharmaceutical and chemical substrates as a matter of public well-being and national security; and (3) encourages the development and enforcement of standards that make the sources of pharmaceuticals and their chemical substrates used in the United States of America transparent to prescribers and the general public. Res. 932, I-19

### **H-100.956, “National Drug Shortages”**

1. Our AMA considers drug shortages to be an urgent public health crisis, and recent shortages have had a dramatic and negative impact on the delivery and safety of appropriate health care to patients. 2. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that are in short supply, and will work in a collaborative fashion

with these and other stakeholders to implement these recommendations in an urgent fashion. 3. Our AMA supports authorizing the Secretary of the U.S. Department of Health and Human Services (DHHS) to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage. 4. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant. 5. The Council on Science and Public Health shall continue to evaluate the drug shortage issue, including the impact of group purchasing organizations on drug shortages, and report back at least annually to the House of Delegates on progress made in addressing drug shortages. 6. Our AMA urges the development of a comprehensive independent report on the root causes of drug shortages. Such an analysis should consider federal actions, the number of manufacturers, economic factors including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and pricing. In particular, further transparent analysis of economic drivers is warranted. The federal Centers for Medicare & Medicaid Services (CMS) should review and evaluate its 2003 Medicare reimbursement formula of average sales price plus 6% for unintended consequences including serving as a root cause of drug shortages. 7. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market due to compliance issues unless such removal is clearly required for significant and obvious safety reasons. 8. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history. 9. Our AMA will collaborate with medical specialty society partners and other stakeholders in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs. 10. Our AMA urges that during the evaluation of potential mergers and acquisitions involving pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to determine whether such an activity has the potential to worsen drug shortages. 11. Our AMA urges the FDA to require manufacturers to provide greater transparency regarding production locations of drugs and provide more detailed information regarding the causes and anticipated duration of drug shortages. 12. Our AMA encourages electronic health records (EHR) vendors to make changes to their systems to ease the burden of making drug product changes. 13. Our AMA urges the FDA to evaluate and provide current information regarding the quality of outsourcer compounding facilities. 14. Our AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine and consider drug shortages as a national security initiative and include vital drug production sites in the critical infrastructure plan. CSAPH Rep. 2, I-11; Modified: CSAPH Rep. 7, A-12; Modified: CSAPH Rep. 2, I-12; Modified: CSAPH Rep. 8, A-13; Modified in lieu of Res. 912, I-13; Modified: CSAPH Rep. 3, A-14; Modified: CSAPH Rep. 2, I-15; Appended: CSAPH Rep. 04, I-17; Modified: CSAPH Rep. 02, A-18

**H-100.966, “Tracking and Punishing Distributors of Counterfeit Pharmaceuticals”**

Our AMA supports legislation making the production and distribution of counterfeit pharmaceuticals a felony. Res. 924, I-03; Reaffirmation I-06; Reaffirmed: BOT Rep. 06, A-16

**H-100.969, “Assuring the Safety and Quality of Foreign-Produced Pharmaceuticals”**

Our AMA supports: (1) the inspection of all foreign manufacturers of pharmaceutical chemicals and products which are exported to the United States to assure compliance with U.S. standards; and (2) periodic surveillance inspections of all foreign pharmaceutical manufacturers with timely follow-up inspection of all foreign manufacturers that have been identified as having serious

manufacturing deficiencies. Res. 512, A-99 Reaffirmation I-06 Reaffirmation A-08 Reaffirmed:  
Res. 508, A-08 Reaffirmation A-09

**H-100.995, “Support of American Drug Industry”**

Our AMA continues to support the American pharmaceutical manufacturing industry in its efforts to develop and market pharmaceutical products meeting proper standards of safety and efficacy for the benefit of the American people.

Sub. Res. 20, A-74; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00;  
Reaffirmed: CSAPH Rep. 1, A-10

**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

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 501  
(N-21)

Introduced by: Washington

Subject: Ensuring Continued Access to Equitable Take-Home Methadone Treatment

Referred to: Reference Committee E

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1 Whereas, The Substance Abuse and Mental Health Services Administration (SAMHSA) issued  
2 an exemption for Opioid Treatment Programs (OTPs) to request 28 days of take-home doses  
3 for stable patients and 14 days of take-home doses for less stable patients, to be given at  
4 provider discretion<sup>1</sup>, in response to the escalating COVID-19 pandemic; and  
5

6 Whereas, Evidence from multiple studies has shown that increases in take-home doses  
7 following the SAMHSA exemption do not lead to worse treatment outcomes, higher overdose  
8 rates, increased healthcare utilization, lack of adherence to treatment, or to significant diversion  
9 of doses among patients on methadone maintenance therapy;<sup>2-5</sup> and  
10

11 Whereas, Engagement with opioid agonist therapy results in improved clinical and community  
12 outcomes for people who use opioids, including reduced risk of overdose, drug use, and crime,  
13 improvements in quality of life, and viral suppression among HIV-positive patients<sup>6-9</sup>; and  
14

15 Whereas, Access to lower-threshold opioid substitution therapy is associated with improved  
16 adherence and treatment outcomes, and decreased overdose rates when compared to usual  
17 care;<sup>10,11</sup> and  
18

19 Whereas, A limited number of federally certified OTPs exist in the United States, causing many  
20 patients to travel long distances to access treatment, which negatively impacts adherence and  
21 retention. Almost 3 million Americans do not have access to a federally certified opioid  
22 treatment program within a 2-hour drive.<sup>12,13</sup> As such, reducing the frequency of which patients  
23 have to make long drives to access their OTP may improve adherence and retention; and  
24

25 Whereas, Clinicians have responded overwhelmingly positively to the modifications in practice  
26 permitted by the SAMHSA exemption, and public health advocates have long argued for  
27 loosening federal guidelines to prevent unnecessary barriers to treatment;<sup>14,15</sup> and  
28

29 Whereas, A report from the George Washington University Regulatory Studies Center  
30 concluded that SAMHSA has the legal authority to extend this flexibility granted during the  
31 COVID-19 public health emergency without additional authorization from Congress;<sup>15</sup> therefore  
32 be it  
33

34 RESOLVED, That our American Medical Association support increasing the interval between  
35 take-home methadone distributions for maintenance and detoxification treatment, per provider  
36 discretion; this may include policy similar to the COVID-era extension policy created by the  
37 Substance Abuse and Mental Health Services Administration (SAMHSA) (New HOD Policy);  
38 and be it further

- 1 RESOLVED, That our AMA utilize the “Good Guidance” petition process to request SAMHSA  
2 modify current policy to reflect the COVID-19 era policy on take-home methadone doses.  
3 (Directive to Take Action)

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

Received: 09/30/21

#### AUTHORS STATEMENT OF PRIORITY

COVID-19 has dramatically impacted our ability to provide appropriate addiction medicine services. At the start of the pandemic, patients who had been prescribed Methadone for Opioid Treatment Program faced challenges accessing their medication due to isolation requirements. As a result, SAMSHA issued exemptions that allow Opioid Treatment Programs to request 28 days of take-home doses of Methadone for stable patients and 14 days of take-home doses for less stable patients, to be prescribed at provider discretion. This change has not shown to have a negative impact on medication compliance or rates of opioid overdose. For patients who live in rural areas or have challenge accessing social support such as transportation, this policy change improves access to life saving treatment. We urge the AMA to advocate for policy that will permanent increase the interval between take-home methadone distributions for maintenance and detoxification treatment, per provider discretion.

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## **RELEVANT AMA POLICY**

### **Methadone Maintenance in Private Practice H-95.957**

Our AMA: (1) reaffirms its position that, "the use of properly trained practicing physicians as an extension of organized methadone maintenance programs in the management of those patients whose needs for allied services are minimal" (called "medical" maintenance) should be evaluated further; (2) supports the position that "medical" methadone maintenance may be an effective treatment for the subset of opioid dependent patients who have attained a degree of behavioral and social stability under standard treatment and thereby an effective measure in controlling the spread of infection with HIV and other blood-borne pathogens but further research is needed; (3) encourages additional research that includes consideration of the cost of "medical" methadone maintenance relative to the standard maintenance program (for example, the cost of additional office security and other requirements for the private office-based management of methadone patients) and relative to other methods to prevent the spread of blood-borne pathogens among intravenous drug users; (4) supports modification of federal and state laws and regulations to make newly approved anti-addiction medications available to those office-based physicians who are appropriately trained and qualified to treat opiate withdrawal and opiate dependence in accordance with documented clinical indications and consistent with sound medical practice guidelines and protocols; and (5) urges that guidelines and protocols for the use of newly approved anti-addiction medications be developed jointly by appropriate national medical specialty societies in association with relevant federal agencies and that continuing medical education courses on opiate addiction treatment be developed by these specialty societies to help designate those physicians who have the requisite training and qualifications to provide therapy within the broad context of comprehensive addiction treatment and management.

Citation: CSA Rep. 2 - I-94; Reaffirmed: CSA Rep. 12 and Append Res. 412, A-99; Reaffirmation I-00; Modified: CSAPH Rep. 1, A-10; Reaffirmed: CSAPH Rep. 01, A-20

### **Enabling Methadone Treatment of Opioid Use Disorder in Primary Care Settings D-95.961**

Our AMA: (1) will research current best practices and support pilot programs and other evidence-based efforts to expand and integrate primary care services for patients receiving methadone maintenance treatment; (2) supports further research to help define the population of patients who may be safely treated with methadone maintenance treatment via office-based treatment, including primary care; and (3) urges all payers, including health insurance companies, pharmacy benefit management companies, and state and federal agencies, to reduce prior authorization and other administrative burdens and to enhance the provision of primary care, counseling, and other medically necessary services for patients being treated with methadone maintenance treatment.

Citation: BOT Rep. 16, I-20

### **Support the Elimination of Barriers to Medication-Assisted Treatment for Substance Use Disorder D-95.968**

1. Our AMA will: (a) advocate for legislation that eliminates barriers to, increases funding for, and requires access to all appropriate FDA-approved medications or therapies used by licensed drug treatment clinics or facilities; and (b) develop a public awareness campaign to increase awareness that medical treatment of substance use disorder with medication-assisted treatment is a first-line treatment for this chronic medical disease.

2. Our AMA supports further research into how primary care practices can implement medication-assisted treatment (MAT) into their practices and disseminate such research in coordination with primary care specialties.

3. The AMA Opioid Task Force will increase its evidence-based educational resources focused on methadone maintenance therapy (MMT) and publicize those resources to the Federation.

Citation: Res. 222, A-18; Appended: BOT Rep. 02, I-19

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 502  
(N-21)

Introduced by: Washington

Subject: Advocating for Heat Exposure Protections for Outdoor Workers

Referred to: Reference Committee E

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- 1 Whereas, Heat-related death is one of the leading causes of death from natural weather or  
2 environmental events<sup>1</sup>; and  
3
- 4 Whereas, During 2004 to 2018, an average of 702 heat-related deaths (415 with heat as the  
5 underlying cause and 287 as a contributing cause) occurred in the United States annually<sup>2</sup>; and  
6
- 7 Whereas, Population exposure to extreme heat has increased over the past several years as a  
8 result of climate change leading to increased heat related morbidity and mortality across the  
9 World<sup>3</sup>; and  
10
- 11 Whereas, As a result of global climate change, heat-related deaths increased by 74% from 1980  
12 to 2016, revealing hotter regions of the world are most likely suffering from an uptick in extreme  
13 heat mortality<sup>4</sup>; and  
14
- 15 Whereas, The recent Pacific Northwest Heat Wave in June 2021 led to over 200 heat-injury  
16 related deaths in Washington and Oregon states over a week-long period<sup>5</sup>; and  
17
- 18 Whereas, Prolonged exposure to extreme heat can cause heat exhaustion, heat cramps, heat  
19 stroke, and death, as well as exacerbate pre-existing chronic conditions including various  
20 respiratory, cerebral, and cardiovascular diseases<sup>6</sup>; and  
21
- 22 Whereas, Prompt treatment of heat-related illnesses with aggressive fluid replacement and  
23 cooling of core body temperature is critical to reducing illness and preventing death<sup>7</sup>; and  
24
- 25 Whereas, According to the Center for Disease Control and Prevention (CDC), despite the fact  
26 that all heat-related deaths and illnesses are preventable, each year an average of about 658  
27 people succumb to extreme heat<sup>2</sup>; and  
28
- 29 Whereas, There are currently 2.4 million farmworkers in the U.S., including 524,000 child  
30 workers<sup>8</sup>; and  
31
- 32 Whereas, Non-U.S. citizens age 18 to 24 were twenty times more likely to die from excessive  
33 heat exposure, than were U.S. citizens in the same age group<sup>1</sup>; and  
34
- 35 Whereas, Since 2010, the Latinx population have accounted for 33% of all heat fatalities, yet  
36 represent only 17% of the U.S. workforce<sup>9</sup>; and



1 Whereas, For many immigrant workers, a population that makes up half of the farm worker  
2 workforce, a combination of factors can make them more vulnerable to heat-related illnesses,  
3 including seasonality, extreme work conditions, a severe lack of knowledge and safety training,  
4 poverty, cultural differences, and language barriers<sup>10</sup>; and  
5

6 Whereas, The CDC provides several evidence based methods for reducing risk of heat related  
7 injury including: staying in an air-conditioned place as much as possible, limiting outdoor activity  
8 to when it's coolest with rest often in shady areas, reducing physical activity in the heat, staying  
9 hydrated, and ensuring that workers are well educated regarding the signs and symptoms of  
10 heat-related illnesses and how to treat them<sup>11</sup>; and  
11

12 Whereas, The United States Military also provides guidelines on evidence-based "Fluid  
13 Replacement and Work/Rest Guide" to protect the country's military workforce against heat  
14 injury by quantifying outdoor temperature, level of activity, and humidity into designated work  
15 and break period recommendations<sup>12</sup>; and  
16

17 Whereas, The CDC's National Institute for Occupational Safety and Health (NIOSH) has long  
18 urged better federal heat injury protections with recommendations that OSHA (Occupational  
19 Safety and Health Administration) write heat-specific protections for workers back in 1975 which  
20 were refined further in 1986 and again in 2016<sup>13</sup>, however none of these recommendations have  
21 been formally adopted into policy; and  
22

23 Whereas, OSHA has not adopted any provisions regarding heat injury protections of workers.  
24 Absent a heat standard, OSHA must rely on a 50-year-old regulation that requires companies to  
25 provide adequate water but not other heat-safety measures<sup>14</sup>; and  
26

27 Whereas, Only 21 states have their own agencies that oversee workplace safety for the private  
28 sector, while the rest rely on the federal OSHA<sup>13</sup>, and  
29

30 Whereas, OSHA will be submitting multiple proposed rules on the topic of Heat Illness  
31 Prevention in Outdoor and Indoor Work Settings in Fall 2021<sup>15</sup>; and  
32

33 Whereas, Current AMA policy lacks the content and specificity to adequately comment on the  
34 upcoming proposed OSHA regulations; and  
35

36 Whereas, the National Institute for Occupational Safety and Health (NIOSH) recommends  
37 several basic heat injury prevention workplace recommendations to protect workers from  
38 morbidity and mortality associated with heat exposure such as establishment of education  
39 programs, implementing acclimatization procedures, ensuring evidence-based hydration  
40 methodology and providing appropriate work breaks in cool, shaded areas<sup>16</sup>; and  
41

42 Whereas, There is currently proposed legislation that has been introduced which would direct  
43 the Occupational Safety and Health Administration (OSHA) to set a federal standard for  
44 protections against heat stress specific to the hazards of the workplace<sup>17</sup>; therefore be it  
45

46 RESOLVED, That our American Medical Association advocate for outdoor workers to have  
47 access to preventative cool-down rest periods in shaded areas for prevention of heat exhaustion  
48 and health educational materials in their primary language (Directive to Take Action); and be it  
49 further

- 1 RESOLVED, That our AMA support legislation creating federal standards for protections against  
2 heat stress specific to the hazards of the workplace including appropriate access to emergency  
3 services at signs and symptoms of heat exposure injury (New HOD Policy); and be it further  
4  
5 RESOLVED, That our AMA work with the United States Department of Labor, the Occupational  
6 Safety and Health Administration, and other appropriate federal stakeholders to develop and  
7 enforce evidence-based policies, guidelines, and protections against heat injury for outdoor  
8 workers independent of legal status. (Directive to Take Action)

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

Received: 09/30/21

#### AUTHORS STATEMENT OF PRIORITY

Our delegation strongly believes that this resolution meets the priority and urgency requirements set out by our Speakers. Over the past few years, there have been rising rates of severe morbidity and mortality related to heat exposure/injury. Our country has seen the devastating impact that excessive heat exposure has on our workforce, and our farmworker population in particular. This past year, heat waves in our country have led to dramatic increases in severe morbidity and mortality rates among the general population. This is an issue of equity as many of our nation's immigrant workers, a population that makes up half of the farm worker workforce, faces a combination of factors increasing vulnerability to heat-related illnesses, including extreme work conditions, safety training, and language barriers. Although it has been recommended by multiple scientific bodies to develop regulations on this issue based on NIOSH recommendations, OSHA has not had a change in policy in over 50 years. It was announced recently, for the first time in over 50 years, that the federal agency OSHA will be producing proposed regulations on labor protections for heat exposure in the fall of 2021. The AMA doesn't have enough specific or appropriate policy to meaningfully participate in conversations and advocacy on this issue. It is critical that the AMA adopt evidence-based policy on this issue to provide public health advocacy for a marginalized population without appropriate labor and public health protections.

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## RELEVANT AMA POLICY

### Heat-Related Illness H-130.951

The AMA recognizes the significant public health threat imposed by heat-related emergencies and provides the following policy: (1) Physicians should identify patients at risk for extreme heat-related illness such as the elderly, children, individuals with physical or mental disabilities, alcoholics, the chronically ill, and the socially isolated. Patients, family members, friends, and caretakers should be counseled about prevention strategies to avoid such illness. Physicians should provide patients at risk with information about cooling centers and encourage their use during heat emergencies. (2) The AMA encourages patients at risk for heat-related illness to consider wearing appropriate medical identification. CSA Rep. 10, A-97; Reaffirmed: CSAPH Rep. 3, A-07; Reaffirmed: CSAPH Rep. 01, A-17.

### Auto Heat Deaths H-15.949

Our American Medical Association supports efforts to reduce deaths of children left in unattended vehicles. Res. 417, A-15.

### 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. CSAPH Rep. 3, I-08; Reaffirmation A-14; Reaffirmed: CSAPH Rep. 04, A-19; Reaffirmation: I-19.

### Occupational Safety and Health Administration Regulations H-365.983

The AMA (1) will work to modify the Occupational Safety and Health Administration regulations on Occupational Exposure to Bloodborne Pathogens to address its practicality and to make physician compliance possible; and (2) in conjunction with other national health provider groups, will work with Congress and other government regulatory agencies to ensure that all decisions regarding the regulation of medical practices be based upon scientific principles and/or fact. Res. 242, I-92; Reaffirmed: BOT Rep. 28, A-03; Reaffirmed: BOT Rep. 28, A-13.

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 503  
(N-21)

Introduced by: Young Physicians Section

Subject: Marketing Guardrails for the “Over-Medicalization” of Cannabis Use

Referred to: Reference Committee E

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1 Whereas, The cannabis-legalization movement has swept the country; and

2  
3 Whereas, In many states, “medical cannabis” and “medical marijuana” laws have put physicians  
4 in the uncomfortable position of being asked to prescribe cannabis for questionable medical  
5 indications; and

6  
7 Whereas, In states where medical cannabis has been legalized, marketing for cannabis for “all  
8 your ills” has become excessive; and

9  
10 Whereas, Emerging research in Colorado has shown that “marijuana use during pregnancy,  
11 concerns related to marijuana in homes with children, and adolescent use should continue to  
12 guide public health education and prevention efforts:

- 13  
14 - The percentage of women who use marijuana in pregnancy ... is higher among  
15 younger women, women with less education, and women with unintended  
16 pregnancies. Marijuana exposure in pregnancy is associated with decreased  
17 cognitive function and attention problems in childhood;  
18  
19 - Unintentional marijuana consumption among children under age 9 continues a  
20 slow upward trend, as do emergency visits due to marijuana. Additionally, an  
21 estimated 23,000 homes with children in Colorado have marijuana stored  
22 potentially unsafely. Marijuana exposures in children can lead to significant  
23 clinical effects that require medical attention;”<sup>1</sup> and  
24

25 Whereas, The American College of Obstetricians and Gynecologists (ACOG) warns that women  
26 who are pregnant or contemplating pregnancy should be encouraged to discontinue marijuana  
27 use, because of concerns regarding impaired neurodevelopment;”<sup>2</sup> and  
28

29 Whereas, Infants exposed to marijuana during pregnancy had a decrease in birth weight,  
30 preterm delivery, and long-term adverse neurodevelopmental effects;<sup>3</sup> and  
31

32 Whereas, In some states, women who are positive for cannabis are restricted from providing  
33 breastmilk to preterm babies in the neonatal intensive care unit; and  
34

35 Whereas, There may be a correlation between heavy cannabis use during adolescence and  
36 neuropsychiatric diseases such as schizophrenia;<sup>4</sup> and

1 Whereas, The U.S. Surgeon General has issued a warning about “Marijuana Use and the  
2 Developing Brain;”<sup>5,6</sup> and

3  
4 Whereas, ACOG has issued a statement discouraging obstetrician–gynecologists from  
5 prescribing or suggesting the use of marijuana for medicinal purposes during preconception,  
6 pregnancy, and lactation;<sup>2</sup> and

7  
8 Whereas, Despite such warnings, cannabis is promoted as a treatment for hyperemesis with  
9 many pregnant women being marketed a neuroactive drug during critical developmental periods  
10 of the embryo and fetus;<sup>7</sup> and

11  
12 Whereas, Two-thirds of Colorado’s cannabis dispensaries recommend marijuana for first  
13 trimester nausea although chronic cannabis use is actually associated with nausea and  
14 vomiting, which leads to emergency department visits;”<sup>1</sup> and

15  
16 Whereas, Marketing cannabis to vulnerable populations like pregnant women and adolescents  
17 can have long-term effects for population health; and

18  
19 Whereas, As an example, the targeted marketing of menthol cigarettes to African-Americans  
20 has led to in 85% of Black smokers using menthol cigarettes compared to 29% of White  
21 smokers and contributing to health disparities;<sup>8</sup> and

22  
23 Whereas, A report by a committee of the Food and Drug Administration concluded that if  
24 menthol cigarettes had been removed from the marketplace in 2010, then (a) by 2020, roughly  
25 17,000 premature deaths would have been avoided and about 2.3 million people would not  
26 have started smoking;<sup>8</sup> and

27  
28 Whereas, Inadequate information about the potential dangers/harms of cannabis (especially  
29 among vulnerable populations) is available, especially amid the storm of pro-cannabis  
30 marketing from that industry; and

31  
32 Whereas, This results in the lay public considering cannabis to be as safe as Tylenol, or carrots;  
33 and

34  
35 Whereas, Regulation of supplements continues to be highly flawed; and

36  
37 Whereas, There are a small number of cannabinoid products (such as marinol) which are  
38 indeed FDA-approved for specific indications; and

39  
40 Whereas, There appears to be a need for “guardrails” for the marketing of cannabis, especially  
41 to protect vulnerable populations; and

42  
43 Whereas, AMA has established policy to seek more data on cannabis, but in the meantime,  
44 cannabis and cannabinoid products are rapidly becoming the “snake oil” of our time; therefore  
45 be it

46  
47 **RESOLVED**, That our American Medical Association send a formal letter to the Food and Drug  
48 Administration and Federal Trade Commission requesting more direct oversight of the  
49 marketing of cannabis for medical use. (Directive to Take Action)

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

Date Received: 09/30/21

#### AUTHORS STATEMENT OF PRIORITY

Marketing Guardrails for the 'Over-Medicalization' of Cannabis Use is being submitted for consideration as a medium-priority resolution. The prevalence of this issue ensures that AMA action would be high impact in terms of public health. Outcomes associated with cannabis use include lower birth weight, increased number of car accidents and other adverse outcomes. Further, limited data on the efficacy of cannabis to treat various medical conditions contribute to ongoing safety concerns. However, given that the issue at hand has been developing over several years, we feel the resolution is timely but not necessarily urgent.

Fiscal note: not yet determined

Date Received: 09/30/21

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#### 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.

6. Our AMA will advocate for urgent regulatory and legislative changes necessary to fund and perform research related to cannabis and cannabinoids.

7. Our AMA will create a Cannabis Task Force to evaluate and disseminate relevant scientific evidence to health care providers and the public.

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; Appended: Res. 913, I-19;

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

Our AMA: (1) believes that cannabis is a dangerous drug and as such is a serious public health concern; (2) believes that the sale of cannabis for adult use should not be legalized (with adult defined for these purposes as age 21 and older); (3) discourages cannabis use, especially by persons vulnerable to the drug's effects and in high-risk populations such as youth, pregnant women, and women who are breastfeeding; (4) believes states that have already legalized cannabis (for medical or adult use or both) should be required to take steps to regulate the product effectively in order to protect public health and safety including but not limited to: regulating retail sales, marketing, and promotion intended to encourage use; limiting the potency of cannabis extracts and concentrates; requiring packaging to convey meaningful and easily understood units of consumption, and requiring that for commercially available edibles, packaging must be child-resistant and come with messaging about the hazards about unintentional ingestion in children and youth; (5) laws and regulations related to legalized cannabis use should consistently be evaluated to determine their effectiveness; (6) encourages local, state, and federal public health agencies to improve surveillance efforts to ensure data is available on the short- and long-term health effects of cannabis, especially emergency department visits and hospitalizations, impaired driving, workplace impairment and worker-related injury and safety, and prevalence of psychiatric and addictive disorders, including cannabis use disorder; (7) supports public health based strategies, rather than incarceration, in the handling of individuals possessing cannabis for personal use; (8) encourages research on

the impact of legalization and decriminalization of cannabis in an effort to promote public health and public safety; (9) encourages dissemination of information on the public health impact of legalization and decriminalization of cannabis; (10) will advocate for stronger public health messaging on the health effects of cannabis and cannabinoid inhalation and ingestion, with an emphasis on reducing initiation and frequency of cannabis use among adolescents, especially high potency products; use among women who are pregnant or contemplating pregnancy; and avoiding cannabis-impaired driving; (11) supports social equity programs to address the impacts of cannabis prohibition and enforcement policies that have disproportionately impacted marginalized and minoritized communities; and (12) will coordinate with other health organizations to develop resources on the impact of cannabis on human health and on methods for counseling and educating patients on the use cannabis and cannabinoids.

Citation: CSAPH Rep. 05, I-17; Appended: Res. 913, I-19; Modified: CSAPH Rep. 4, I-20;

### **Cannabis Legalization for Medicinal Use D-95.969**

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

Citation: CSAPH Rep. 05, I-17; Appended: Res. 211, A-18; Appended: CSAPH Rep. 3, I-19;



AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 504  
(N-21)

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

Subject: Air Pollution and COVID: A Call to Tighten Regulatory Standards

Referred to: Reference Committee E

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1 Whereas, The Environmental Protection Agency (EPA) is in the process of reviewing the current  
2 National Ambient Air Quality Standards (NAAQS) for fine particulate matter (particles with a  
3 diameter of  $\leq 2.5 \mu\text{m}$  [PM<sub>2.5</sub>]) -- that is, levels not exceeding an annual average of 12  $\mu\text{g}$  per  
4 cubic meter and a 24-hour average of 35  $\mu\text{g}$  per cubic meter; and

5  
6 Whereas, The current EPA guidelines are not sufficient to protect public health, since exposure to  
7 ambient PM<sub>2.5</sub> at the current accepted EPA levels is estimated to be responsible for tens of  
8 thousands of premature deaths in the United States each year<sup>1</sup>; and

9  
10 Whereas, Current AMA policy calls for more stringent standards than are currently followed by the  
11 EPA as noted in the policy summary below; and

12  
13 Whereas, Air pollution is known to correlate with numerous other adverse health outcomes also,  
14 including heart disease, stroke, asthma, COPD, and neurodegenerative disorders; and air  
15 pollution disproportionately affects vulnerable populations and communities of color<sup>1</sup>; and

16  
17 Whereas, Results suggest that exposure to traffic-related air pollution is associated with  
18 dementia, via both direct neural damage as well as indirect pathways related to diabetes and  
19 metabolic dysfunction; and

20  
21 Whereas, Nearly all deaths attributable to air pollution in the contiguous United States are  
22 associated with ambient air pollution concentrations below the current EPA standards, a finding  
23 that both reflects past success and suggests that more stringent PM<sub>2.5</sub> air quality standards may  
24 further reduce the national death toll associated with air pollution; and

25  
26 Whereas, Vulnerable populations and communities of color are most at risk for negative health  
27 impacts from particulate air pollution owing to their location near emission sources or to  
28 demographic or clinical characteristics (e.g., age or disease status) that increase their  
29 susceptibility<sup>1</sup>; and

30  
31 Whereas, Despite many improvements since passage of the Clean Air Act in 1970, according to a  
32 report from the National Bureau of Economic Research, "After declining by 24.2% from 2009 to  
33 2016, annual average fine particulate matter (PM<sub>2.5</sub>) in the United States in counties with  
34 monitors increased by 5.5% between 2016 and 2018;" and

35  
36 Whereas, Former members of the EPA Clean Air Scientific Advisory Committee on Particulate  
37 Matter (which was dissolved on October 10, 2018), who now make up the nongovernmental  
38 Independent Particulate Matter Review Panel, unequivocally and unanimously concluded that the  
39 current PM<sub>2.5</sub> standards do not adequately protect public health<sup>1</sup>; and

1 Whereas, A recent health impact assessment modeling a 40% reduction in PM<sub>2.5</sub> exposure  
2 estimated a drop in mortality by > 100,000 among adults in the Continental United States; and  
3

4 Whereas, Increased mortality due to COVID-19 has been shown in studies at Harvard and in the  
5 Netherlands to be associated with air pollution: an increase of 1ug/m<sup>3</sup> of PM 2.5 was shown to be  
6 associated with an 8% increase in the COVID-19 death rate in the US, and a 16% increase in the  
7 death rate due to COVID-19 in the Netherlands; and  
8

9 Whereas, Indoor air pollution in the COVID-19 era has demonstrated unequivocally to be a  
10 much greater source of viral transmission than outdoor pollution by CDC, EPA and other  
11 agencies, recently resulting in recommended improvements in ventilation and air filtering; and<sup>1</sup>  
12

13 Whereas, COVID-19 has also disproportionately affected vulnerable populations and communities  
14 of color where there has been a higher burden of disease and higher mortality; therefore be it  
15

16 RESOLVED, That our American Medical Association advocate for stronger federal particulate  
17 matter air quality standards and improved enforcement that will better protect the public's  
18 health. (Directive to Take Action)

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

Received: 10/06/21

#### AUTHORS STATEMENT OF PRIORITY

Air pollution is ubiquitous. It affects all physicians and all patients. [On June 10, 2021, EPA announced](#) it will re-evaluate the current air quality standards for particulate matter (PM) with a proposal to follow in Spring 2022. Thus, the need for advocacy on this issue is imminent, urgent and timely. The current guidelines are not sufficient to protect public health. Nearly all deaths attributable to air pollution in the US are associated with air pollution below the current standards. Vulnerable populations and communities of color are most at risk due to their locations living close to high emission sources. Furthermore, increased mortality due to COVID-19 is associated with air pollution, both which disproportionately affect vulnerable populations. As climate change leads to increased wildfires, another major source of PM, it becomes even more imperative that we advocate for stronger federal PM air quality standards and improved enforcement to reduce the modifiable sources of air pollution.

<sup>1</sup> Ventilation and Coronavirus (COVID-19) | US EPA Residential ([ashrae.org](http://ashrae.org))

#### References

Link that is most pertinent: <https://www.epa.gov/pm-pollution/national-ambient-air-quality-standards-naaqs-pm>

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<sup>2</sup> Paul KC, Haan M, Yu Y, et al. Traffic-Related Air Pollution and Incident Dementia: Direct and Indirect Pathways Through Metabolic Dysfunction. *J Alzheimers Dis.* 2020;76(4):1477-1491. doi:10.3233/JAD-200320

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<sup>4</sup> NBER WORKING PAPER SERIES, "RECENT INCREASES IN AIR POLLUTION: EVIDENCE AND IMPLICATIONS FOR MORTALITY," K Clay et al. <http://www.nber.org/papers/w26381>

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<sup>7</sup> IM Cole et al "Air Pollution and COVID-19 in Dutch Municipalities, *Envir Resource Econ* Aug 4 2020  
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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 505  
(N-21)

Introduced by: Medical Student Section

Subject: Representation of Dermatological Pathologies in Varying Skin Tones

Referred to: Reference Committee E

- 
- 1 Whereas, Worse healthcare outcomes result from the under recognition of dermatologic  
2 pathologies, such as erythema migrans and the late detection of melanoma in individuals with  
3 darker skin tones – also known as Fitzpatrick skin types III-VI<sup>1-4</sup>; and  
4
- 5 Whereas, There is a higher probability that individuals with darker skin tones have late detection  
6 of disease when compared to lighter skin tones (Fitzpatrick skin types I-II)<sup>5-8</sup>; and  
7
- 8 Whereas, There is a lack of targeted skin cancer awareness and prevention efforts for patients  
9 with darker skin tones<sup>9</sup> resulting in lower rates of skin cancer screening; and  
10
- 11 Whereas, Research has demonstrated that patients with darker skin tones feel frustrated when  
12 dermatologists do not demonstrate competency recognizing and treating pathologies on darker  
13 skin<sup>10</sup>; and  
14
- 15 Whereas, It has been shown that overrepresentation of minority group skin tones relative to  
16 their proportion in the population is required to achieve equitable diagnostic outcomes<sup>11-13</sup>; and  
17
- 18 Whereas, About 75 percent of dermatological imagery in medical textbooks represent  
19 individuals with lighter skin tones while core dermatology textbooks used to educate trainees,  
20 dermatologists, and generalists have limited representations of skin of color<sup>14</sup>; and  
21
- 22 Whereas, Terms such as “Classic Presentation” are usually examples of lighter skin tones<sup>15</sup>;  
23 and  
24
- 25 Whereas, Although our AMA recognizes the importance of racial and ethnic disparities in  
26 healthcare (H-350.974), the terms “race” and “ethnicity” are not equivalent nor interchangeable  
27 with the genotypic and phenotypic characteristics of “skin tone”<sup>16-18</sup>; and  
28
- 29 Whereas, Existing AMA policy “promote[s] education on the importance of skin cancer  
30 screening and skin cancer screening in patients of color” (H-55.972) but lacks policy to ensure  
31 medical students are adequately primed to recognize such pathologies in a variety of skin  
32 colors; and  
33
- 34 Whereas, While current AMA policy supports ensuring diversity in United States Medical  
35 Licensing Examination exam test/oversight committees representative of the test takers  
36 (D-275.963), this policy does not cover diversity in test questions themselves, nor the  
37 importance of skin tone as a relevant pathological factor missing in dermatological exam  
38 questions; therefore be it

- 1 RESOLVED, That our American Medical Association encourage the inclusion of a diverse range  
2 of skin tones in preclinical and clinical dermatologic medical education materials and evaluation  
3 (New HOD Policy); and be it further  
4  
5 RESOLVED, That our AMA encourage the development of educational materials for medical  
6 students and physicians that contribute to the equitable representation of diverse skin tones  
7 (New HOD Policy); and be it further  
8  
9 RESOLVED, That our AMA support the overrepresentation of darker skin tones in dermatologic  
10 medical education materials. (New HOD Policy)

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

Date Received: 09/30/21

#### AUTHORS STATEMENT OF PRIORITY

Racism remains a strong influence woven into much of medicine. The reckoning with long-standing racism that began in summer 2020 has also touched medicine, where the urgency of this reckoning is compounded by the knowledge that medical racism and racism built into the structures and institutions of medicine causes deaths every day. One such institution is the underrepresentation of darker skin tones in dermatological teaching and references. The lack of exposure to presentations of various skin tones leads to misdiagnoses or missed diagnoses for people with darker skin, further exacerbating disparities.

Our AMA has a long and shameful history of participating in and exacerbating medical racism, but in recent times our organization has made admirable strides toward trying to repair its past damage and show itself to be a leader on the road to greater health equity. Our delegation believes the AMA's commitment to This resolution provides tangible steps forward for our AMA to demonstrate our continued commitment to reducing and combating the harms of racism in medicine, and maybe even preventing them.

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## RELEVANT AMA POLICY

### Early Detection and Prevention of Skin Cancer H-55.972

Our AMA: (1) encourages all physicians to (a) perform skin self-examinations and to examine themselves and their families on the first Monday of the month of May, which is designated by the American Academy of Dermatology as Melanoma Monday; (b) examine their patients' skins for the early detection of melanoma and nonmelanoma skin cancer; (c) urge their patients to perform regular self-examinations of their skin and assist their family members in examining areas that may be difficult to examine; and (d) educate their patients concerning the correct way to perform skin self-examination; (2) supports mechanisms for the education of lay professionals, such as hairdressers and barbers, on skin self-examination to encourage early skin cancer referrals to qualified health care professionals; and (3) supports and encourages prevention efforts to increase awareness of skin cancer risks and sun-protective behavior in communities of color. Our AMA will continue to work with the American Academy of Dermatology, National Medical Association and National Hispanic Medical Association and public health organizations to promote education on the importance of skin cancer screening and skin cancer screening in patients of color.

CCB/CLRPD Rep. 3, A-14

### Educating Medical Students in the Social Determinants of Health and Cultural Competence H-295.874

Our AMA: (1) Supports efforts designed to integrate training in social determinants of health, cultural competence, and meeting the needs of underserved populations across the undergraduate medical school curriculum to assure that graduating medical students are well prepared to provide their patients safe, high quality and patient-centered care. (2) Supports faculty development, particularly clinical faculty development, by medical schools to assure that faculty provide medical students' appropriate learning experiences to assure their cultural competence and knowledge of social determinants of health. (3) Supports medical schools in their efforts to evaluate the effectiveness of their social determinants of health and cultural competence teaching of medical students, for example by the AMA serving as a convener of a consortium of interested medical schools to develop Objective Standardized Clinical Exams for use in evaluating medical students' cultural competence. (4) Will conduct ongoing data gathering, including interviews with medical students, to gain their perspective on the integration of social determinants of health and cultural competence in the undergraduate medical school curriculum. (5) Recommends studying the integration of social determinants of health and cultural competence training in graduate and continuing medical education and publicizing successful models.

CME Rep. 11, A-06, Reaffirmation A-11, Modified in lieu of Res. 908, I-14, Reaffirmed in lieu of Res. 306, A-15, Reaffirmed: BOT Rep. 39, A-18, Modified: CME Rep. 01, A-20

### **Racial and Ethnic Disparities in Health Care H-350.974**

1. Our AMA recognizes racial and ethnic health disparities as a major public health problem in the United States and as a barrier to effective medical diagnosis and treatment. The AMA maintains a position of zero tolerance toward racially or culturally based disparities in care; encourages individuals to report physicians to local medical societies where racial or ethnic discrimination is suspected; and will continue to support physician cultural awareness initiatives and related consumer education activities. The elimination of racial and ethnic disparities in health care an issue of highest priority for the American Medical Association.

2. The AMA emphasizes three approaches that it believes should be given high priority:

A. Greater access - the need for ensuring that black Americans without adequate health care insurance are given the means for access to necessary health care. In particular, it is urgent that Congress address the need for Medicaid reform.

B. Greater awareness - racial disparities may be occurring despite the lack of any intent or purposeful efforts to treat patients differently on the basis of race. The AMA encourages physicians to examine their own practices to ensure that inappropriate considerations do not affect their clinical judgment. In addition, the profession should help increase the awareness of its members of racial disparities in medical treatment decisions by engaging in open and broad discussions about the issue. Such discussions should take place in medical school curriculum, in medical journals, at professional conferences, and as part of professional peer review activities.

C. Practice parameters - the racial disparities in access to treatment indicate that inappropriate considerations may enter the decision making process. The efforts of the specialty societies, with the coordination and assistance of our AMA, to develop practice parameters, should include criteria that would preclude or diminish racial disparities

3. Our AMA encourages the development of evidence-based performance measures that adequately identify socioeconomic and racial/ethnic disparities in quality. Furthermore, our AMA supports the use of evidence-based guidelines to promote the consistency and equity of care for all persons.

4. Our AMA: (a) actively supports the development and implementation of training regarding implicit bias, diversity and inclusion in all medical schools and residency programs; (b) will identify and publicize effective strategies for educating residents in all specialties about disparities in their fields related to race, ethnicity, and all populations at increased risk, with particular regard to access to care and health outcomes, as well as effective strategies for educating residents about managing the implicit biases of patients and their caregivers; and (c) supports research to identify the most effective strategies for educating physicians on how to eliminate disparities in health outcomes in all at-risk populations.

CLRPD Rep. 3, I-98, Appended and Reaffirmed: CSA Rep.1, I-02, Reaffirmed: BOT Rep. 4, A-03, Reaffirmed in lieu of Res. 106, A-12, Appended: Res. 952, I-17, Reaffirmed: CMS Rep. 10, A-19; Reaffirmed: CMS Rep. 3, A-21

### **Ensuring Diversity in United States Medical Licensing Examination Exams D-275.963**

Our AMA will pursue diversity on all United States Medical Licensing Examination test/oversight committees in order to include the perspectives from others, including international medical graduates, to better reflect the diversity of the test takers.

Sub. Res. 306, A-09, Reaffirmed: CME Rep. 01, A-19

### **Continued Support for Diversity in Medical Education D-295.963**

Our AMA will: (1) publicly state and reaffirm its stance on diversity in medical education; (2) request that the Liaison Committee on Medical Education regularly share statistics related to compliance with accreditation standards IS-16 and MS-8 with medical schools and with other stakeholder groups; (3) work with appropriate stakeholders to commission and enact the recommendations of a forward-looking, cross-continuum, external study of 21st century medical education focused on reimagining the future of health equity and racial justice in medical education, improving the diversity of the health workforce, and ameliorating inequitable outcomes among minoritized and marginalized patient populations; (4) advocate for funding to support the creation and sustainability of Historically Black College and University (HBCU), Hispanic-Serving Institution (HSI), and Tribal College and University (TCU) affiliated medical schools and residency programs, with the goal of achieving a physician workforce that is proportional to the racial, ethnic, and gender composition of the United States population; and (5) work with appropriate stakeholders to study reforms to mitigate demographic and socioeconomic inequities in the residency and fellowship selection process, including but not limited to the selection and reporting of honor society membership and the use of standardized tools to rank applicants, with report back to the House of Delegates.

Res. 325, A-03, Appended: CME Rep. 6, A-11, Modified: CME Rep. 3, A-13; Appended: CME Rep. 5, A-21

AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 506  
(N-21)

Introduced by: Medical Student Section

Subject: Enhancing Harm Reduction for People Who Use Drugs

Referred to: Reference Committee E

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1 Whereas, Overdose is the leading cause of preventable death in the USA and has contributed  
2 to an unprecedented decline in life expectancy among certain demographics; in 2018, the age-  
3 adjusted death rate from drug overdose in the USA was 17.1 per 100,000, which is almost 3  
4 times what it was in 2010<sup>1-3</sup>; and

5  
6 Whereas, The majority of overdose fatalities from 2014-2017 involved opioids<sup>1</sup>; and

7  
8 Whereas, High potency opioids such as fentanyl that have entered the drug supply have played  
9 a major role in recent increases in overdose deaths<sup>1,4-6</sup>; and

10  
11 Whereas, Across the 10 states participating in the CDC's 2016 Enhanced State Opioid  
12 Overdose Surveillance (ESOOS) program, fentanyl was detected in over half of all opioid  
13 overdose deaths, and, of the deaths involving fentanyl, fentanyl was determined to contribute to  
14 death in 97.1% of cases<sup>7</sup>; and

15  
16 Whereas, Most people who are using fentanyl-contaminated drugs do not know that they  
17 contain fentanyl<sup>8</sup>, nor are they seeking to use fentanyl, and a pilot drug checking program found  
18 that of 907 samples expected to be heroin only 160 (17.6%) contained the expected substance,  
19 and 822 (90.6%) tested positive for fentanyl<sup>4,8</sup>; and

20  
21 Whereas, Fentanyl is not the only adulterant commonly found in the illicit drug supply, and other  
22 psychoactive adulterants such as benzodiazepines, non-fentanyl synthetic opioids, stimulants,  
23 and synthetic cannabinoids are also present and can contribute to health risks and overdose<sup>10</sup>;  
24 and

25  
26 Whereas, Potentially harmful adulterants, including fentanyl, have been identified in multiple  
27 classes of illegal drugs, including heroin, cocaine, methamphetamine, and counterfeit  
28 prescription pills; people using the drugs do not know which products contain adulterants, which  
29 increases risk of adverse events<sup>9,11</sup>; and

30  
31 Whereas, The use of novel synthetic opioids that include fentanyl analogs and non-fentanyl  
32 compounds have resulted in a spike in overdose deaths<sup>12</sup>; and

33  
34 Whereas, Drug-checking technologies, such as fentanyl test strips, allow people who use drugs  
35 to check what drugs and potential adulterants are contained in the substance they purchased<sup>13</sup>;  
36 and

37  
38 Whereas, Fentanyl test strips are a relatively inexpensive testing modality and multiple studies  
39 have demonstrated high uptake and acceptance of fentanyl test strips among people who use  
40 drugs<sup>13-17</sup>; and



1 Whereas, Although concerns have arisen that drug checking technologies such as fentanyl  
2 strips will “enable fentanyl seeking behavior”, it has been found that a positive test strip result  
3 was associated with a higher intention to decrease fentanyl dosage<sup>18,19</sup>; and  
4

5 Whereas, There is an association between test strip use and overdose risk-reducing behaviors,  
6 including disposing of the drug, not using alone, and having naloxone on hand while using<sup>12-17,19-</sup>  
7 <sup>21</sup>; and  
8

9 Whereas, Although drug-checking technologies are associated with positive health outcomes  
10 and decreased overdose rates, limitations, including their current illegality, have been identified  
11 as a major barrier to their implementation and use<sup>22,23</sup>; and  
12

13 Whereas, Forty-four US states have laws which qualify any drug testing equipment, including  
14 fentanyl testing strips, as illegal paraphernalia<sup>24,25</sup>; and  
15

16 Whereas, Legislation providing an exemption to existing paraphernalia laws for all drug-  
17 checking technologies has been enacted in various states including Maryland, Washington DC,  
18 and Illinois, and preliminary results have shown the use of drug-checking technology to be  
19 effective in helping people use drugs more safely<sup>23,26</sup>; and  
20

21 Whereas, Multiple states, including California and Utah, have piloted and used State and private  
22 funds to promote the use and distribution of fentanyl testing strips with outcomes showing  
23 participants taking steps to reduce their risk of overdose<sup>27-31</sup>; and  
24

25 Whereas, Use of federal funds for fentanyl testing strips was approved in April 2021<sup>32</sup>; and  
26

27 Whereas, Experts believe that the decriminalization of drug checking technologies in the USA  
28 will be associated with decreases in overdose rates<sup>19,23</sup>; and  
29

30 Whereas, People who inject drugs (PWID) are at higher risk of contracting and transmitting  
31 infectious diseases (e.g. HBV, HCV, and HIV) via blood exposure due to the practice of sharing  
32 injection supplies<sup>33,34</sup>; and  
33

34 Whereas, Syringe exchange programs (SEPs) were developed to reduce the harms associated  
35 with injection drug use and multiple studies across the USA indicate that SEPs are associated  
36 with significant decreases in risky injection practices and bloodborne infections such as HIV<sup>35-38</sup>;  
37 and  
38

39 Whereas, Although most discussions of risks related to injection drug use focus on syringes and  
40 needles, PWID require more than just needles and syringes: injection drug preparation  
41 equipment (IDPE) includes items such as cookers, water containers, and filters<sup>39,40</sup>; and  
42

43 Whereas, PWID are increasingly making use of SEPs to obtain safe injecting equipment<sup>41</sup>; and  
44

45 Whereas, The majority of SEPs explicitly state that they supply needles, syringes, and offer a  
46 place to deposit used needles<sup>42</sup>; and  
47

48 Whereas, SEPs may, but are not required to, provide other equipment needed to prepare and  
49 consume drugs such as filters, mixing containers, and sterile water<sup>43</sup>; and  
50

51 Whereas, HIV and HCV transmission can occur via sharing of IDPE even when  
52 needles/syringes are not shared<sup>39,44</sup>; and

1 Whereas, Not using fresh IDPE is associated with MRSA-related infectious endocarditis and  
2 other viral and bacterial infections in drug users<sup>40,45</sup>; and  
3

4 Whereas, CDC best practices state that SEPs, as they are implemented, should be a part of a  
5 comprehensive service program that includes, as appropriate: provision of sterile needles,  
6 syringes and other drug preparation equipment (purchased with non-federal funds) and disposal  
7 services<sup>46</sup>; and  
8

9 Whereas, Individuals are more likely to reuse injection materials if they fear arrest for  
10 possession of drug paraphernalia<sup>47</sup>; and  
11

12 Whereas, As of 2019, 32 states allow SEPs to operate in exception to state drug paraphernalia  
13 laws<sup>48</sup>; and  
14

15 Whereas, The majority of current state laws allowing for SEP operation only specify the  
16 distribution of needles and syringes, thus the inclusion of IDPE in these programs is not  
17 explicitly protected despite being an independent harm reduction measure<sup>48-49</sup>; therefore be it  
18

19 RESOLVED, That our American Medical Association amend Policy D-95.987, "Prevention of  
20 Opioid Overdose," by addition and deletion as follows:  
21

22 D-95.987 – PREVENTION OF OPIOID DRUG-RELATED OVERDOSE

23 1. Our AMA: (A) recognizes the great burden that ~~opioid addiction and prescription drug~~  
24 ~~abuse~~ substance use disorders (SUDs) and drug-related overdoses and death places  
25 on patients and society alike and reaffirms its support for the compassionate treatment  
26 of ~~such~~ patients with a SUD and people who use drugs; (B) urges that community-  
27 based programs offering naloxone and other opioid overdose and drug safety and  
28 prevention services continue to implemented in order to further develop best practices  
29 in this area; ~~and~~ (C) encourages the education of health care workers and people who  
30 use drugs ~~opioid users~~ about the use of naloxone and other harm reduction measures  
31 in preventing opioid and other drug-related overdose fatalities; and (D) will continue to  
32 monitor the progress of such initiatives and respond as appropriate.

33 2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their  
34 caregivers in the signs and symptoms of ~~opioid a drug-related~~ overdose; and (B)  
35 encourage the continued study and implementation of appropriate treatments and risk  
36 mitigation methods for patients at risk for ~~opioid a drug-related~~ overdose.

37 3. Our AMA will support the development and implementation of appropriate education  
38 programs for persons receiving treatment for a SUD or in recovery from opioid addiction  
39 a SUD and their friends/families that address harm reduction measures ~~how a return to~~  
40 ~~opioid use after a period of abstinence can, due to reduced opioid tolerance, result in~~  
41 ~~overdose and death.~~

42 4. Our AMA will advocate for and encourage state and county medical societies to  
43 advocate for harm reduction policies that provide civil and criminal immunity for the use  
44 of "drug paraphernalia" designed to support safe use of drugs, including drug  
45 contamination testing and injection drug preparation, use, and disposal supplies.

46 (Modify Current HOD Policy)

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

Date Received: 09/30/21

#### AUTHORS STATEMENT OF PRIORITY

Though COVID-19 has taken most of the headlines, the opioid epidemic has been a persistent issue facing the nation that continues to worsen and that has been exacerbated by the pandemic. Further, chemical adulterants such as synthetic opioids are increasing in prevalence in non-opioid drugs. Over the last decade, mitigation efforts, such as syringe exchange programs (SEPs) have been established to promote safe use and recovery for people who inject drugs (PWID). However, current paraphernalia laws limit harm reduction measures that SEPs can provide as well as simple chemical tests that people who use drugs could utilize to promote safer use by detecting adulterants. One harm reduction measure would be to exempt SEP distribution of cookers and other preparation equipment which can harbor hepatitis C and HIV from paraphernalia laws. Another harm reduction measure is to exempt use of drug checking technologies as studies have shown decreased use when there is a known adulterant in the drug product. The most prescient example of this are fentanyl test strips, a cheap and effective testing modality which has recently been given federal funding and piloted by cities and counties across the country. This resolution seeks to amend D-95.987 to encompass overdose as due to more than just opioids and to support initiatives to protect individuals who are using harm reduction measures, such as providing fresh IDPE and using drug checking technologies from criminal and civil prosecution under drug paraphernalia laws, to better address the ongoing tragedy of the opioid crisis.

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## RELEVANT AMA POLICY

### Prevention of Opioid Overdose D-95.987

1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse places on patients and society alike and reaffirms its support for the compassionate treatment of such patients; (B) urges that community-based programs offering naloxone and other opioid overdose prevention services continue to be implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and opioid users about the use of naloxone in preventing opioid overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.

2. Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid overdose.

3. Our AMA will support the development and implementation of appropriate education programs for persons in recovery from opioid addiction and their friends/families that address how a return to opioid use after a period of abstinence can, due to reduced opioid tolerance, result in overdose and death.

Res. 526, A-06; Modified in lieu of Res. 503, A-12; Appended: Res. 909, I-12; Reaffirmed: BOT Report. 22, A-16; Modified: Res. 511, A-18; Reaffirmed: Res. 235, I-18

### Drug Paraphernalia H-95.989

The AMA opposes the manufacture, sale and use of drug paraphernalia.

BOT Rep. N, A-82; Reaffirmed: Sub Res. 108, A-87; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03; Reaffirmed: CSAPH Rep. 1, A-13

### Syringe and Needle Exchange Programs H-95.958

Our AMA: (1) encourages all communities to establish needle exchange programs and physicians to refer their patients to such programs; (2) will initiate and support legislation providing funding for needle exchange programs for injecting drug users; and (3) strongly encourages state medical associations to initiate state legislation modifying drug paraphernalia laws so that injection drug users can purchase and possess needles and syringes without a prescription and needle exchange program employees are protected from prosecution for disseminating syringes.

Res. 231, I-94; Reaffirmed Ref Cmt. D, I-96; Modified by CSA Rep. 8, A-97; Reaffirmed: CSAPH Rep. 3, A-07; Modified: Res. 203, A-13; Modified: Res. 914, I-16

### Dispelling Myths of Bystander Opioid Overdose D-95.965

Our AMA will work with appropriate stakeholders to: (1) develop and disseminate educational materials aimed at dispelling the fear of bystander overdose via inhalation or dermal contact with fentanyl or other synthetic derivatives; and (2) identify those professions, such as first responders, most impacted by opioid overdose deaths in order to provide targeted education to dispel the myth of bystander overdose via inhalation or dermal contact with fentanyl or other synthetic derivatives.

Res. 532, A-19

#### **Opioid Mitigation D-95.964**

Our AMA: (1) encourages relevant federal agencies to evaluate and report on outcomes and best practices related to federal grants awarded for the creation of Quick Response Teams and other innovative local strategies to address the opioid epidemic, and will share that information with the Federation; and (2) will update model state legislation regarding needle and syringe exchange to state and specialty medical societies.

BOT Rep. 09, I-19

#### **The Reduction of Medical and Public Health Consequences of Drug Abuse H-95.954**

Our AMA: (1) encourages national policy-makers to pursue an approach to the problem of drug abuse aimed at preventing the initiation of drug use, aiding those who wish to cease drug use, and diminishing the adverse consequences of drug use; (2) encourages policy-makers to recognize the importance of screening for alcohol and other drug use in a variety of settings, and to broaden their concept of addiction treatment to embrace a continuum of modalities and goals, including appropriate measures of harm reduction, which can be made available and accessible to enhance positive treatment outcomes for patients and society; (3) encourages the expansion of opioid maintenance programs so that opioid maintenance therapy can be available for any individual who applies and for whom the treatment is suitable. Training must be available so that an adequate number of physicians are prepared to provide treatment. Program regulations should be strengthened so that treatment is driven by patient needs, medical judgment, and drug rehabilitation concerns. Treatment goals should acknowledge the benefits of abstinence from drug use, or degrees of relative drug use reduction; (4) encourages the extensive application of needle and syringe exchange and distribution programs and the modification of restrictive laws and regulations concerning the sale and possession of needles and syringes to maximize the availability of sterile syringes and needles, while ensuring continued reimbursement for medically necessary needles and syringes. The need for such programs and modification of laws and regulations is urgent, considering the contribution of injection drug use to the epidemic of HIV infection; (5) encourages a comprehensive review of the risks and benefits of U.S. state-based drug legalization initiatives, and that until the findings of such reviews can be adequately assessed, the AMA reaffirm its opposition to drug legalization; (6) strongly supports the ability of physicians to prescribe syringes and needles to patients with injection drug addiction in conjunction with addiction counseling in order to help prevent the transmission of contagious diseases; and (7) encourages state medical associations to work with state regulators to remove any remaining barriers to permit physicians to prescribe needles for patients.

CSA Rep. 8, A-97; Reaffirmed: CSA Rep. 12, A-99; Appended: Res. 416, A-00; Reaffirmation: I-00; Reaffirmed: CSAPH Rep. 1, A-10; Modified: CSAPH Rep. 2, I-13