#### **DISCLAIMER**

The following is a preliminary report of actions taken by the House of Delegates at its November 2021 Special Meeting and should not be considered final. Only the Official Proceedings of the House of Delegates reflect official policy of the Association.

# AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES (November 2021 Meeting)

Report of Reference Committee E

E. Christopher Bush, MD, Chair

Your reference committee recommends the following consent calendar for acceptance:

## **RECOMMENDED FOR ADOPTION AS AMENDED**

- 1. Council on Science and Public Health Report 4 Pharmacovigilance (Res 518-A-19, Chemical Variability in Pharmaceutical Products)
- 2. Resolution 502 Advocating for Heat Exposure Protections for Outdoor Workers
- 3. Resolution 506 Enhancing Harm Reduction for People Who Use Drugs

## RECOMMENDED FOR ADOPTION IN LIEU OF

4. Resolution 505 – Representation of Dermatological Pathologies in Varying Skin Tones

\*For CSAPH 4 and Resolution 506, the double underline and double strikethrough that are traditional format for indicating amendments from the Reference Committee are difficult to discern. Therefore, the Reference Committee has also highlighted these additions in yellow.

# **Amendments**

If you wish to propose an amendment to an item of business, click here: <u>Submit New Amendment</u>

1

2

4 5

6

7 8

9 10

11 12

13 14

15

# RECOMMENDED FOR ADOPTION AS AMENDED

(1) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 4 – PHARMACOVIGILANCE (RES 518-A-19, CHEMICAL VARIABILITY IN PHARMACEUTICAL PRODUCTS)

## **RECOMMENDATION A:**

Recommendation 2 in Council on Science and Public Health Report 4 be <u>amended by addition</u> to read as follows:

- 2. That Policy H-120.958, "Supporting Safe Medical Products as a Priority Public Health Initiative" be amended by addition and deletion to read as follows:
  - 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, including 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' and pharmacists' knowledge and awareness of the program and encouraging proper reporting of adverse events;
  - (4) vigorously work to support the Drug Supply Chain and Security Act (DSCSA, Public Law 113-54), including provisions on product identification and verification, data sharing, detection and response, 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 2030 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), with pharmacy associations, 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) Healthcare Research and Quality (AHRQ) and the Centers for Medicare & Medicaid Services (CMS) to provide information to individual physicians, pharmacists, other clinicians, and state medical societies on the need for public health infrastructure and local consortiums to work on problems related to medical product safety. (Modify Current HOD Policy)

## **RECOMMENDATION B:**

 The recommendations in Council on Science and Public Health Report 2 be <u>adopted as amended</u> and the remainder of the report be <u>filed</u>.

HOD ACTION: The recommendations in Council on Science and Public Health Report 2 <u>adopted as amended</u> and the remainder of the report <u>filed.</u>

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

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

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

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

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, including 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 the Drug Supply Chain and Security Act (DSCSA, Public

 (4) vigorously work to support the Drug Supply Chain and Security Act (DSCSA, Public Law 113-54), including provisions on product identification and verification, data sharing, detection and response, 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 2030 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) Healthcare Research and Quality (AHRQ) 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. (Modify Current HOD Policy)
- 3. That Policy D-100.977, "Pharmaceutical Quality Control for Foreign Medications," that calls upon Congress to provide the FDA with the necessary authority and resources to ensure that imported drugs are safe for American consumers and patients, be reaffirmed. (Reaffirm HOD Policy)
- That Policy D-100.985, "Federal Regulation and Computerized Tracking of Pharmaceuticals During Shipping and Handling from Manufacture Until Ultimately Received by Patient," opposing illegal drug diversion, illegal Internet sales of drugs, illegal importation of drugs, and drug counterfeiting, be reaffirmed. (Reaffirm HOD Policy)
- 5. That Policy D-100.988, "Tracking and Punishing Distributors of Counterfeit Pharmaceuticals," supporting the FDA's efforts to evaluate and facilitate implementation of effective tracking systems for pharmaceuticals, be reaffirmed. (Reaffirm HOD Policy)
- 6. That Policy H-100.946, "Source and Quality of Medications Critical to National Health and Security," supporting 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 encouraging 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, be reaffirmed. (Reaffirm HOD Policy)
- 7. That Policy H-100.969, "Assuring the Safety and Quality of Foreign-Produced Pharmaceuticals," supporting 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, be reaffirmed. (Reaffirm HOD Policy)
- That Policy H-100.995, "Support of American Drug Industry," supporting 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, be reaffirmed. (Reaffirm HOD Policy)

Your Reference Committee heard limited but unanimously supportive testimony related to Council on Science and Public Health (CSAPH) Report 4. The National Institutes of Health, while supportive of the report, offered a few amendments to include pharmacists and other clinicians who play a critical role to ensure the safe use of medications. CSAPH and your Reference Committee agree that the proposed amendments strengthen the recommendations of the report. Therefore, your Reference Committee recommends that Council on Science and Public Health Report 4 be adopted as amended.

(2) RESOLUTION 502 – ADVOCATING FOR HEAT EXPOSURE PROTECTIONS FOR OUTDOOR WORKERS

#### **RECOMMENDATION A:**

Resolution 502 be be <u>amended by addition and deletion</u> to read as follows:

RESOLVED, That our American Medical Association (AMA) advocate for <u>all</u> eutdoor workers to have access to preventative cool-down rest periods in shaded, <u>ventilated</u>, <u>and/or cooled</u> areas for prevention of <u>injury from sun exposure and heat injury as well as appropriate access to emergency services when signs and symptoms of heat exposure injury appear exhaustion and health educational materials in their primary language (Directive for Action); and be it further</u>

RESOLVED, That our AMA <u>advocate for support</u> legislation <u>that creates creating</u> federal standards for protections against heat stress <u>and sun exposure</u> specific to the hazards of the workplace <u>including appropriate access to emergency services at signs and symptoms of heat exposure injury</u> (New HOD Policy); and be it further

RESOLVED, That our AMA support policy change at the federal level via legislation or administrative rule changes by the Occupational Safety and Health Administration (OSHA) that would require that workers receive health educational materials about prevention and recognition of heat exhaustion and heat exposure injury that is in the worker's primary language (New HOD Policy); and be it further

RESOLVED, That our AMA work with the United States Department of Labor, the Occupational Safety and Health Administration OSHA, and other appropriate federal stakeholders to develop and enforce evidence-based policies, guidelines, and protections against heat injury for outdoor workers independent of legal status. (Directive for Action); and be it further

 RESOLVED, That our AMA recognize there are particular medical conditions and medications, including but not limited to psychotropics, which increase an individual's vulnerability to the negative impacts of heat and sun exposure and advocate for recognition of this, as well as additional protections as

part of any guidelines, legislation or other policies. (New HOD Policy)

**RECOMMENDATION B:** 

Resolution 502 be adopted as amended.

**RECOMMENDATION C:** 

That the title of Resolution 502 be changed.

ADVOCATING FOR HEAT EXPOSURE PROTECTIONS FOR ALL WORKERS

HOD ACTION: Resolution 502 <u>adopted as amended</u> with a change in title to read:

ADVOCATING FOR HEAT EXPOSURE PROTECTIONS FOR ALL WORKERS

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

RESOLVED, That our AMA support legislation creating federal standards for protections against heat stress specific to the hazards of the workplace including appropriate access to emergency services at signs and symptoms of heat exposure injury (New HOD Policy); and be it further

RESOLVED, That our AMA work with the United States Department of Labor, the Occupational Safety and Health Administration, and other appropriate federal stakeholders to develop and enforce evidence-based policies, guidelines, and protections against heat injury for outdoor workers independent of legal status. (Directive for Action)

Your Reference Committee heard unanimously supportive testimony for the intent of Resolution 502. Several amendments were proffered to improve the language of the resolution. Several amendments were suggested to expand the scope to include all workers at risk of heat exposure, both those indoor and outdoor. Other proposed amendments recommend specifically including sun as a risk factor. Another amendment proposed acknowledges that some medications or medical conditions may increase an individual's risk of heat- or sun-exposure related illness. Your Reference Committee agrees that these amendments strengthen the Resolution and have incorporated all of them. Therefore, your Reference Committee recommends that Resolution 502 be adopted as amended with a change in title.

(3) RESOLUTION 506 – ENHANCING HARM REDUCTION FOR PEOPLE WHO USE DRUGS

# RECOMMENDATION A:

1

2

3 4

5 6

7

8 9

10 11

12

13

14

15 16

17 18

19

20

21

22 23

24

25

26

27

28

29

30

31

32

33

34

35

36

37

38

39

40 41

42

43

44

45

46

Resolution 506 be be <u>amended by addition and deletion</u> to read as follows:

RESOLVED, That our American Medical Association (AMA) amend policy D-95.987 by addition and deletion as follows: D-95.987, "Prevention of Opioid Drug-related Overdose"

- 1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse substance use disorders (SUDs) and drug-related overdoses and death places on patients and society reaffirms alike and its support for compassionate treatment of such patients with a SUD and people who use drugs; (B) urges that community-based programs offering naloxone and other opioid overdose and drug safety and prevention services continue to implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and people who use drugs opioid users about the use of naloxone and other harm reduction measures in preventing opioid and other drugrelated overdose fatalities; and (D) will continue to monitor the progress of such initiatives and respond as appropriate.
- Our AMA will: (A) advocate for the appropriate education of at-risk patients and their caregivers in the signs and symptoms of opioid a drug-related overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid a drug-related overdose.
- Our AMA will support the development and implementation of appropriate education programs for persons <u>receiving treatment for a SUD or</u> in recovery from <del>opioid addiction</del> <u>a SUD</u> and their friends/families that address <u>harm reduction</u> <u>measures</u> how a return to opioid use after a period of abstinence can, due to reduced opioid tolerance, result in overdose and death.

4. Our AMA will advocate for and encourage state and county medical societies to advocate for harm reduction policies that provide civil and criminal immunity for the use of "drug paraphernalia" designed to for harm reduction from drug use support safe use of drugs, including but not limited to drug contamination testing and injection drug preparation, use, and disposal supplies. (Modify HOD Policy)

### **RECOMMENDATION B:**

Resolution 506 be adopted as amended.

HOD ACTION: Resolution 506 adopted as amended.

RESOLVED, That our American Medical Association (AMA) amend policy D-95.987 by addition and deletion as follows: D-95.987, "Prevention of Opicid Drug-related Overdose"

- 1. Our AMA: (A) recognizes the great burden that opioid addiction and prescription drug abuse substance use disorders (SUDs) and drug-related overdoses and death places on patients and society alike and reaffirms its support for the compassionate treatment of such patients with a SUD and people who use drugs; (B) urges that community-based programs offering naloxone and other opioid overdose and drug safety and prevention services continue to implemented in order to further develop best practices in this area; and (C) encourages the education of health care workers and people who use drugs opioid users about the use of naloxone and other harm reduction measures in preventing opioid and other drug-related 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 a drug-related overdose; and (B) encourage the continued study and implementation of appropriate treatments and risk mitigation methods for patients at risk for opioid a drug-related overdose.
- 3. Our AMA will support the development and implementation of appropriate education programs for persons receiving treatment for a SUD or in recovery from opioid addiction a SUD and their friends/families that address harm reduction measures how a return to opioid use after a period of abstinence can, due to reduced opioid tolerance, result in overdose and death.
- 4. Our AMA will advocate for and encourage state and county medical societies to advocate for harm reduction policies that provide civil and criminal immunity for the use of "drug paraphernalia" designed to support safe use of drugs, including drug contamination testing and injection drug preparation, use, and disposal supplies.

(Modify HOD Policy)

Your Reference Committee heard largely supportive testimony regarding the intent of Resolution 506. Minor amendments were offered to clarify the focus on harm reduction and safe use of drugs while not allowing for misinterpretation that the AMA supports use of illicit drugs. An additional amendment was offered include an additional Resolve statement about the usage of the term "syringe exchange programs" in further AMA communications. While your Reference Committee thinks this is an important topic, we feel it is not germane to include with this policy. AMA Policy H-95.958, "Syringe and Needle Exchange Programs" specifically

deals with the issue, and we recommend the submission of a new Resolution at a later meeting to address this important topic directly. Furthermore, a commentor noted opposition to this Resolution because it would eliminate opioid overdose-specific policy from the AMA database. Your Reference Committee would like to note that other AMA policies address opioid-specific issues, including D-95.965, "Dispelling Myths of Bystander Opioid Overdose" and D-95.964, "Opioid Mitigation." Your Reference Committee agrees that the proffered amendments are important and that AMA policy should reflect the changing nature of illicit drug use and overdose. Therefore, your Reference Committee recommends that Resolution 506 be adopted as amended.

5

6

(4)

# 7 8 9

11 12 13

14

10

# 15 16 17 18

19 20 21

## 22 23 24

25

31 32 33

30

35 36

34

49

# RECOMMENDED FOR ADOPTION IN LIEU OF

**RESOLUTION 505 – REPRESENTATION OF** DERMATOLOGICAL PATHOLOGIES IN VARYING SKIN TONES

## **RECOMMENDATION:**

That Alternate Resolution 505 be adopted lieu of Resolution 505.

RESOLVED, That our American Medical Association encourage comprehensive, inclusive and equitable representation of a diverse range of skin tones in all dermatologic and other relevant medical educational resources for medical students, physicians, nonphysician healthcare providers and patients. (New HOD Policy)

**HOD ACTION: Alternate Resolution 505 adopted lieu of** Resolution 505.

RESOLVED, That our American Medical Association (AMA) encourage the inclusion of a diverse range of skin tones in preclinical and clinical dermatologic medical education materials and evaluation (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage the development of educational materials for medical students and physicians that contribute to the equitable representation of diverse skin tones (Directive to Take Action); and be it further

RESOLVED, That our AMA support the overrepresentation of darker skin tones in dermatologic medical education materials. (New HOD Policy)

Your Reference Committee heard overwhelmingly supportive testimony related to original Resolution 505 submitted by the Medical Student Section, but several commentors noted the problematic language of "overrepresentation" in Resolve 3. Several amendments were offered in an attempt to clarify the language, others recommended that Resolve 3 be eliminated because Resolves 1 and 2 successful convey the intent of the Resolution, and still others proffered an alternate Resolution that they believe to be simplified, unambiguous, and allencompassing. Your Reference Committee agrees that some of the language in the original Resolution was problematic. While the author was able to provide an excellent discussion of why the term "overrepresentation" should be included, your Reference Committee believes that amended language would prevent future confusion. Additional amendments were put forth that asked for the Resolution be expanded to include a fourth Resolve clause calling for increased efforts to diversify the dermatology workforce. While this amendment received other supportive testimony, your Reference Committee feels that improved diversity in the dermatology workforce would best be addressed in a separate Resolution, Therefore, your

- Reference Committee recommends that alternate Resolution 505 be adopted in lieu of Resolution 505. 1 2

- 1 This concludes the report of Reference Committee E. I would like to thank Jessica Adkins,
- 2 MD, Ricardo Correa, MD, Oluwasegun Paul Emenogu, Jeff Klingman, MD, David Teuscher,
- 3 MD, Yasser Zeid, MD, and all those who testified before the Committee as well as our AMA
- 4 staff.

Jeff Klingman, MD (Alternate) Jessica Adkins, MD California Medical Association Sectional Resident and Fellow Kentucky Medical Association David Teuscher, MD (Alternate) Ricardo Correa, MD American College of Physicians American Academy of Orthopaedic American Medical Association Political Surgeons Action Committee (AMPAC) Oluwasegun Paul Emenogu Yasser Zeid, MD (Alternate) Regional Medical Student **Texas Medical Association** Ohio State Medical Association E. Christopher Bush, MD (Alternate) Michigan State Medical Society

Chair