# **Reference Committee E**

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# REPORT OF THE BOARD OF TRUSTEES

	Subject:	Over-the-Counter Contraceptive Drug Access (Resolution 110-A-17)			
	Presented by:	Gerald E. Harmon, MD, Chair			
	Referred to:	Reference Committee E (Douglas Martin, MD, Chair)			
1 2 3 4 5	INTRODUCTI	INTRODUCTION			
	At the 2017 Annual Meeting, Resolution 110-A-17, "Over-the-Counter Contraceptive Drug Access," introduced by the Illinois Delegation and referred by the House of Delegates (HOD), asked:				
7 8 9	That our American Medical Association (AMA) condemn age-based, cost-based, and other non-medical barriers to contraceptive drug access;				
9 10 11 12 13 14 15 16	That our AMA adopt policy supporting equitable access to over-the-counter (OTC) contraception, including those forms of contraception recommended for OTC sale, patient risk assessment screening tools, and prescribing by non-physicians;				
	That our AMA support policy solutions that prohibit cost-sharing obstacles to OTC contraceptive drug access, and full coverage of all contraception without regard to prescription or OTC utilization, since all contraception is essential preventive health care; and				
17 18 19 20	That our AMA advocate for the legislative and/or regulatory mechanisms needed to achieve improvements for OTC contraceptive drug access and quality.				
This report outlines the issues associated with OTC contraceptive drug access and provid recommendation based on current evidence. Access to emergency contraception is not a f this report.		ines the issues associated with OTC contraceptive drug access and provides a on based on current evidence. Access to emergency contraception is not a focus of			
24 25 26	5 BACKGROUND				
27 28 29 30 31 32 33	Unintended pregnancy is a major public health issue in the United States accounting for approximately 45% of all pregnancies and is associated with increased risks for negative outcomes for mothers and infants and increased health care costs. <sup>1</sup> Currently, OTC oral contraception is available in more than 100 countries. Although no OTC oral contraceptives are available in the United States, interest in their availability is high, with surveys finding that 62% of U.S. women support such access. <sup>2</sup>				
34 35 36 37	Oral contraceptive pills consist of the hormones estrogen and/or progestin and are taken orally once per day. Three types are available in the United States: the combination pill with estrogen and progestin, the progestin-only pill, and the continuous use pill. The three types of oral contraceptives vary in their hormonal composition and the regimen for their use. <sup>3</sup> Emergency contraceptive pills,				

which consist of the progestin levonorgestrel, are also considered a type of oral contraceptive not 1 2 intended for daily use, but that can be used to prevent pregnancy after unprotected sex.<sup>3</sup> Oral contraceptives are primarily used for pregnancy prevention, but they are also used to treat other 3 4 health conditions such as menstrual pain, irregular menstruation, fibroids, endometriosis-related 5 pain, menstrual-related migraines, and acne.<sup>3</sup> 6 7 Policy statements from the American Academy of Family Physicians (AAFP), the American 8 College of Obstetricians and Gynecologists (ACOG), and American Public Health Association (APHA) support OTC oral contraceptive access.<sup>4-6</sup> An Oral Contraceptives Over-the-Counter 9 10 Working Group was formed in 2004 with the aims "to improve access to contraception and reduce 11 disparities in reproductive health outcomes by making a low-cost oral contraceptive product 12 available OTC in the United States." Over 80 organizations have signed onto the Working Group's 13 statement of purpose, including the American Academy of Pediatrics and ACOG.<sup>7</sup> 14 15 A variety of concerns have been raised in discussions of OTC oral contraceptives, including barriers to access, cost of a potential OTC oral contraceptive, and safety, which are briefly 16 17 discussed below. 18 19 BARRIERS TO CONTRACEPTIVE USE 20 21 One third of women at risk for unintended pregnancy who attempted to obtain a prescription for contraception reported having trouble doing so.<sup>8</sup> Access and cost issues are the most commonly 22 23 cited reasons why women do not use oral contraceptives, use them inconsistently, or discontinue 24 use early. Women may experience difficulty obtaining oral contraceptives for a variety of reasons 25 including the prescription requirement, lack of insurance, and inaccessibility when travelling. Research suggests that OTC access would increase the use of contraception and facilitate 26 27 continuity of use.<sup>9</sup> Additional time and cost benefits include less travel, fewer physician office visits, and less time off work. 28 29 30 INSURANCE COVERAGE AND ACCESS 31 32 Under the Patient Protection and Affordable Care Act (ACA), most private health insurance plans 33 are required to provide coverage for at least one product in each of the 18 contraceptive methods 34 approved by the U.S. Food and Drug Administration (FDA) for women with no cost-sharing.<sup>10</sup> This coverage also applies to OTC contraceptives used by women, such as emergency 35 contraception, barrier methods, and spermicide, but a prescription is required.<sup>11</sup> Plans are not 36 required to cover male contraception methods such as vasectomy and male condoms. Federal law 37 38 requires Medicaid programs to cover family planning services and supplies without cost-sharing. 39 States that expanded Medicaid under the ACA must follow the ACA requirements for oral 40 contraceptives. Coverage for oral contraceptives is required in the Indian Health Service and in the 41 TRICARE program, but is not a requirement for Medicare. Regulations exist to exclude some or all 42 contraceptive methods and services from health plans provided by employers who morally object 43 to oral contraceptive use or have religious exemptions. However, enforcement of these regulations

- 44 has been blocked by the courts.
- 45
- 46 Cost is an important consideration. A survey of U.S. women indicated that the maximum they are
- 47 willing to pay for an OTC oral contraceptive is \$20.<sup>2</sup> A cost modeling analysis determined that full
- 48 insurance coverage of an OTC oral contraceptive without any out-of-pocket expenses would result
- 49 in the largest reduction of unintended pregnancies.<sup>12</sup> The analysis also found that use would be
- 50 highest, and the estimated reduction in unintended pregnancy greatest, among low-income women,
- 51 if an OTC oral contraceptive was fully covered by insurance with no cost-sharing. Full coverage

would also be cost effective for insurers because of the savings associated with averting unintended 1 2 pregnancies.<sup>12</sup> AAFP, ACOG, and APHA policy statements include support for insurance coverage 3 of OTC contraceptive products without the need for a prescription. Federal or state legislative or 4 administrative changes to ACA policy would be needed to include non-prescribed contraceptives in 5 coverage and pharmacies would need billing mechanisms for processing claims without a 6 prescription. Billing mechanisms that do not rely on a prescription are used by Medicaid programs 7 in several states to cover OTC emergency contraception. These billing mechanisms have been 8 incorporated into existing software, and it may be feasible for additional insurers to incorporate the 9 ability to process claims without a prescription. Computerized kiosks providing a prescription for 10 contraception after the completion of a self-screening tool are currently being piloted, and the potential exists for women to be able to generate a prescription in a pharmacy or at home using 11 web-based tools from insurers.<sup>13</sup> Congress has introduced legislation addressing this issue, and a 12 few states have passed laws requiring insurers to cover OTC contraceptives without a prescription.<sup>3</sup> 13 14 15 Concerns have been raised that overall access to oral contraceptives may be hindered if an OTC 16 product becomes available and the switch negatively affects insurance coverage for other prescription oral contraceptives or creates new barriers to obtaining these products.<sup>13</sup> Insurers may 17 18 employ formulary management strategies such as preferred drug lists, prior authorization, and steptherapy programs.<sup>13</sup> 19 20 Some states allow pharmacists to provide oral contraceptives without physician oversight. Policies 21 22 in such states vary including age requirements, type of contraceptive allowed, and length of supply. 23 Some discussion has centered around the issue of increasing the dispensing period of oral 24 contraceptives to a 12-month supply to facilitate access. Dispensing requirements vary by insurer 25 and laws requiring coverage for a 12-month supply have been passed in several states.<sup>3</sup> Additionally, online services and smartphone applications have emerged for women to speak with 26 27 providers via video, obtain prescriptions, and order oral contraceptives from mail delivery services. 28 Requirements and cost vary based on the application.<sup>3</sup> 29 30 SELF-SCREENING 31 32 In 2016, the U.S. Centers for Disease Control and Prevention (CDC) published an updated Medical Eligibility Criteria for Contraceptive Use (U.S. MEC), an evidence-based list of conditions and 33 34 medications considered contraindications to contraceptive methods. The U.S. MEC states that all 35 contraindications for combined oral contraceptives, other than hypertension, can be identified by 36 reviewing a woman's medical history; progestin-only oral contraceptives have a shorter list of 37 contraindications that does not include hypertension.<sup>1,14</sup> 38 39 Concern has been raised from physicians that women might not be able to self-diagnose 40 contraindications associated with oral contraceptives or may ignore label warnings. Studies have 41 shown that women can accurately use checklists to determine if they have contraindications to 42 hormonal contraception; in one study, 96% of cases evaluated demonstrated agreement between a 43 women's assessment of her contraindications using a checklist and a clinician's independent evaluation, and women often take a more conservative approach compared with clinicians.<sup>15,16</sup> 44 45 46 Another concern that has been voiced about OTC oral contraceptives is that women would not 47 obtain recommended preventive screenings for cervical and breast cancer and for sexually

- 47 obtain recommended preventive screenings for cervical and oreast cancer and for sexually 48 transmitted infections that often accompany physician visits for contraceptives. The World Health
- transmitted infections that often accompany physician visits for contraceptives. The world He
- Organization, FDA, and ACOG state that oral contraceptives can be safely and effectively
   prescribed without a pelvic examination. Although experts have stated that that preventive
- 50 prescribed without a pervice examination. Although experts have stated that that preventive 51 screening is not medically necessary or required for the provision of hormonal contraception,<sup>17</sup>

many clinicians continue to link the services.<sup>18</sup> A recent study found that a high proportion of 1

2 women in Texas who acquired oral contraceptives from Mexico without a prescription obtained

3 screening tests at a rate higher than the U.S. national average.<sup>19</sup>

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# AGE RESTRICTIONS

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7 Adolescents face age-related barriers to contraception access, which could be reduced with OTC 8 access, including concerns about disclosing their confidential information and their ability to access 9 services without the consent of a parent or guardian. An age restriction for an OTC product is 10 uncommon, but is a relevant topic related to OTC oral contraceptives. Some states that allow 11 pharmacists to provide oral contraceptives include age restrictions in their policy. When 12 levonorgestrel emergency contraception became available OTC, there was an age restriction that 13 was later removed. The consensus is that oral contraceptives are safe and the prevalence of 14 contraindications is greater in women 35 years and older compared to younger users and is low among women of all ages for a progestin-only product.<sup>5,15</sup> 15

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17 A 2011 survey revealed that most women do not support an age restriction for oral contraceptives 18 and a survey of teenagers found that approximately three-quarters supported oral contraceptive OTC access.<sup>8,20</sup> Additionally, studies showed that sexual risk-taking behaviors did not increase in 19 20 teenagers when their access to emergency contraception increased, and the increased access may aid in improving their use of more effective contraception methods.<sup>21</sup> 21

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#### 23 FDA APPROVAL PATHWAY

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25 The FDA has pathways in place for the development and regulation of OTC products, the monograph process or the New Drug Application (NDA) process. Products for which an OTC 26 27 monograph does not exist or that do not conform to an existing final monograph, as is the case for 28 oral contraceptives, primarily use the NDA process. A sponsor seeking to market a product OTC,

either as a new NDA or a switch from a prescription product, applies to the Division of 29

30 Nonprescription Drug Products in the Office of Drug Evaluation IV.<sup>22</sup>

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32 Once a sponsor submits an NDA to change one oral contraceptive product that is already registered 33 as a prescription product to an OTC product, there are consumer studies, safety data evaluations, 34 and regulatory reviews required by the FDA. The required information includes the following:

- 35 Post-market safety data review: Toxicity data, addictive properties, and interactions with • 36 other drugs are evaluated to establish the safety of the medication as a prescription product.
- Label comprehension study: Ability of potential users to understand OTC labeling of 37 • 38 medication and take the medication as indicated without a physician's explanation are 39 evaluated.
- 40 Self-selection study: Ability of potential users to determine whether the product is • 41 appropriate for them is evaluated.
  - Actual use study: Correct use of the product by potential users in a simulated OTC • environment is evaluated.
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Human factors study: Interacting with the product by potential users is evaluated.

46 Following collection and submission of data, FDA staff reviews and evaluates the findings in 47 consultation with an advisory committee. Many of the required studies can occur simultaneously;

48 however, this process can take three to four years from NDA initiation until an application is

49 approved. Evidence published in peer-reviewed literatures suggests that oral contraceptives

50 generally meet FDA requirements for an OTC switch.<sup>23</sup> 1 Over fifty formulations, accounting for hundreds of different branded products of oral

2 contraceptives, exist as prescription medications. Only the specific product for which an NDA was

3 submitted will be evaluated for OTC sale. All others would remain as prescription medications

4 unless an NDA or Abbreviated New Drug Application (ANDA), in the case of a generic with the

5 same drug formulation, is submitted and required studies are individually performed for each one.

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7 Progestin-only oral contraceptives have fewer and more rare contraindications than combined oral 8 contraceptives, which may make them a better candidate for FDA approval for OTC sale. A 9 progestin-only product has been put forward as a potential first candidate for an OTC oral 10 contraceptive. In December 2016, Ibis Reproductive Health announced a partnership with HRA 11 Pharma to conduct the research needed and submit an application to the FDA to bring a progestinonly oral contraceptive pill to the Unites States OTC market.<sup>24</sup> The 2006 FDA approval of OTC 12 sale for progestin-only levonorgestrel emergency contraception, which contains a higher dose of 13 14 progestin than is found in oral contraceptives, may make it easier to obtain approval for an OTC 15 progestin-only product than for a combined oral contraceptive product.<sup>13</sup>

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17 CURRENT AMA POLICY

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19 Several current AMA policies address contraceptives. Policy D-75.995, "Over-the-Counter Access 20 to Oral Contraceptives," directs our AMA to recommend to the FDA that manufacturers of oral 21 contraceptives be encouraged to submit the required application and supporting evidence for the 22 Agency to consider approving a switch in status from prescription to OTC for such products and 23 encourages the continued study of issues relevant to over-the-counter access for oral 24 contraceptives. Policy H-75.990, "Development and Approval of New Contraceptives," encourages 25 manufacturers to conduct post-marketing surveillance studies of contraceptive products. Policy H-75.998, "Opposition to HHS Regulations on Contraceptive Services for Minors," opposes 26 27 regulations that require parental notification when prescription contraceptives are provided to 28 minors through federally funded programs, since they create a breach of confidentiality in the 29 physician-patient relationship. Policy H-180.958, "Coverage of Prescription Contraceptives by 30 Insurance," supports federal and state efforts to require that every prescription drug benefit plan 31 include coverage of prescription contraceptives. Policy H-75.987, "Reducing Unintended 32 Pregnancy," urges health care professionals to provide care, assistance, and education for women 33 of reproductive age, supports reducing unintended pregnancies as a national goal, and supports the 34 training of all primary care physicians and relevant allied health professionals in the area of preconception counseling. Policies H-75.985, "Access to Emergency Contraception," and 35 36 D-75.997, "Access to Emergency Contraception," support the access to emergency contraception.

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# 38 CONCLUSION

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An FDA pathway exists for the conversion of prescription products, such as oral contraceptives, to
 OTC products if manufacturers submit the required application and data. A potential first candidate
 for an OTC progestin-only oral contraceptive product was recently announced by a manufacturer

because progestin-only products have fewer contraindications than other types of oralcontraceptives.

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46 Research has shown that women support the idea of OTC oral contraceptives and can effectively

47 self-screen for their use. Additionally, removing the prescription access barrier to oral

48 contraceptives would increase and facilitate continuity of use. Full insurance coverage, without

49 cost sharing, of an OTC oral contraceptive would likely result in the largest reduction of

50 unintended pregnancies as well as cost effectiveness for insurers. However, concerns regarding

1 2 3	hin stra	drance of ategies ex	f overall access to oral contraceptives because of insurance formulary management ist.
4 5	RE	COMME	ENDATIONS
6 7 8	The the	e Board o remainde	of Trustees recommends the following be adopted in lieu of Resolution 110-A-17, and er of the report be filed:
9 10 11 12 13 14 15 16 17 18 19	1.	That our D-75.99 <u>Our</u> 1.	AMA amend Policy D-75.995, "Over-the-Counter Access to Oral Contraceptives;" 5, Over-the-Counter Access to Oral Contraceptives <u>AMA:</u> <u>Our AMA Encourages will recommend to the US Food and Drug Administration that</u> manufacturers of oral contraceptives <del>be encouraged</del> to submit the required application and supporting evidence to the US Food and Drug Administration for the Agency to consider approving a switch in status from prescription to over-the-counter for such products. <u>Our AMA</u> Encourages the continued study of issues relevant to over-the-counter access for oral contraceptives. (Modify Current HOD Policy)
20 21 22 23 24 25 26 27	2.	That our Insurance H-12 <u>1.</u> <u>2.</u>	AMA amend Policy H-180.958, "Coverage of Prescription Contraceptives by be;" 80.958, Coverage of Prescription Contraceptives by Insurance Our AMA supports federal and state efforts to require that every prescription drug benefit plan include coverage of prescription contraceptives. Our AMA supports full coverage, without patient cost-sharing, of all contraception without regard to prescription or over-the-counter utilization because all contraception is essential preventive health care. (Modify Current HOD Policy)

Fiscal Note: Less than \$500

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# REPORT OF THE BOARD OF TRUSTEES

B of T Report 22-A-18

	Subject: In-Flight Emergencies (Resolution 516-A-17, Resolve 3)				
	Presented by:	Gerald E. Harmon, MD, Chair			
	Referred to: Reference Committee E (Douglas Martin, MD, Chair)				
1	INTRODUCTI	INTRODUCTION			
2 3 4 5	<ul> <li>At the AMA House of Delegates 2017 Annual Meeting, Resolve 3 of Resolution 516-A-17, "</li> <li>Flight Emergencies,"<sup>1</sup> introduced by the Minority Affairs Section and referred by the House of Delegates (HOD), asked:</li> </ul>				
7 8 9	That our American Medical Association (AMA) support and advocate for a requirement that fight crews will no longer be required to verify a medical professional's credentials before allowing that person to assist with an inflight medical emergency (IFME).				
10 11 12 13 14 15	The original resolution explains that in instances of heart failure a lack of oxygen can cause brain damage in only a few minutes. "A person may die within 8 to 10 minutes and may experience cognitive deficits if deprived of oxygen for greater than 4 minutes." Thus, the extra time it would take for flight staff to verify credentials of a passenger offering to render emergency medical assistance during an IFME could lead to a negative patient outcome.				
10 17 18 19 20	This report will outline the current requirements concerning the verification of a medical professional's credentials in the event of an IFME and existing AMA policies on physician identification of credentials and delivery of health care by Good Samaritans.				
20 21 22	BACKGROUND				
22 23 24	The Aviation Medical Assistance Act of 1998				
24 25 26 27 28 29 30	Currently there is no federal law mandating that air carriers verify medical credentials or identification before allowing medical professionals to assist in emergency situations The law only requires that air carriers believe in good faith that an emergency volunteer is medically qualified, in order to not be liable for damages arising out of the acts or omissions of the passenger (e.g., a physician passenger) rendering assistance of a passenger during an IFME. In relevant part, the Aviation Medial Assistance Act of 1998 states that:				
32 33 34 35	SECTION 5. LIMITATIONS ON LIABILITY. (a) Liability of Air CarriersAn air carrier shall not be liable for damages in any action brought in a Federal or State court arising out of the performance of the air carrier in obtaining or attempting to obtain the assistance of a passenger in an in-flight medical emergency, or out of the acts or omissions of the passenger				

rendering the assistance, if the passenger is not an employee or agent of the carrier and the
 carrier in good faith believes that the passenger is a medically qualified individual.

3 4

**Online** Forum

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6 A comment on Resolution 516 was provided by a physician on the online forum. The commenting 7 physician expressed opposition to the resolution for a number of reasons. First, he drew from 8 personal experience and explained that a customary procedure already exists for a physician to 9 come forth with the appropriate medical documents before treating an individual. Next, he 10 explained that there are enough examples of individuals who attempt to act as a physician without credentials to justify having a flight crew member verify identification in order to protect patients. 11 12 He also explained that credentialing should not be taken lightly. Lastly, he highlighted that most 13 commercial flights today have Wi-Fi capability and crews can easy and quickly check credentials 14 with state medical boards online. Note, the commenting physician interprets the requirement for 15 verification of a physician's credentials as requiring either physical identification or by validation through an online credential inquiry. As noted above, the law only requires good faith belief by an 16 17 air carrier that the passenger who volunteers to render assistance during an IFME is a medically 18 gualified individual. In practice, this could mean viewing physical identification or online 19 credentials or, could be achieved by requiring only a verbal statement by such passenger 20 concerning his or her credentials before allowing the passenger to provide assistance during an 21 IFME.

- 22
- 23 Relevant Current AMA Policy
- 24

25 Extensive AMA policies address IFMEs. Current AMA Policy H-45.997, "In-Flight Emergency Care," supports legislative provisions that grant any physician, other medical professional, or 26 27 airline employee, acting in the role of a Good Samaritan during an in-flight medical emergency, an 28 umbrella of immunity against legal or personal redress by the airline, the passengers, or the persons 29 involved in the medical emergency. Policy H-45.978, "In-Flight Medical Emergencies," discusses 30 in-flight emergency medical supplies and equipment and implementation of comprehensive in-31 flight emergency medical systems that ensure direct supervision by physicians with appropriate training in emergency and aerospace medicine. Policy H-45.979, "Air Travel Safety," encourages 32 actions to support education of physicians on available options if asked to render assistance during 33 34 an IFME to encourage full and effective participation when an IFME occurs.

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36 In addition, there are existing AMA policies that address physician identification generally and 37 during emergencies specifically. Policy H-405.987, "Identification of Board Certified Physicians," urges physicians to identify themselves by stating the full name of their certifying board. Note, 38 39 Policy H-405.987 only requires a verbal statement of credentials. Policy H-130.937, "Delivery of 40 Health Care by Good Samaritans," describes basic guidelines to apply in instances where a physician happens upon the scene of an emergency and desires to assist and render medical 41 42 assistance. Policy H-130.937 states, in part that it is the obligation of the bystander physician to 43 provide reasonable self-identification. This policy refers to situations in which a bystander 44 physician, parallel to an in-flight emergency physician, volunteers to provide emergency aid in 45 collaboration with EMS providers. While flight crews are not EMS providers or medical experts this policy is instructive. Similar to the EMS team and physician, an in-flight physician and flight 46 crew may have to "work collaboratively" in assessing the medical emergency and providing 47 48 reasonable self-identification is appropriate. Note Policy H-130.937 only requires verbal or hand 49 signal verification of self-identification, not verification via physical identification or an online 50 credential inquiry.

## 1 CONCLUSION

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Based on existing federal law (which does not require verification of medical credentials during an
 IFME), AMA policies described in this report, and industry guidelines on the topic of IFMEs and

4 IFME), AMA policies described in this report, and industry guidelines on the topic of IFMEs and 5 physician identification during medical emergencies, the Board of Trustees believes further efforts

6 on this topic by our AMA are not necessary. It is reasonable for air carriers to determine the level

and manner of verification of medical credentials (which could be achieved by a verbal statement)

- 8 to establish a good faith belief that the passenger is a medically qualified individual before
- 9 allowing a passenger to provide assistance during an IFME. This position would be consistent with
- 10 existing AMA policies.
- 11
- 12 RECOMMENDATION
- 13
- 14 The Board of Trustees recommends existing AMA Policy H-45.979, "Air Travel Safety," be
- 15 reaffirmed in lieu of Resolve 3, Resolution 516-A-17, and the remainder of the report be filed.

Fiscal Note: Less than \$500

#### REFERENCES

#### H-45.978, "In-Flight Medical Emergencies"

Our AMA urges: (1) urges that decisions to expand the contents of in-flight emergency medical kits and place emergency lifesaving devices onboard commercial passenger aircraft be based on empirical data and medical consensus; in-flight medical supplies and equipment should be tailored to the size and mission of the aircraft, with careful consideration of flight crew training requirements; and (2) the Federal Aviation Administration to work with appropriate medical specialty societies and the airline industry to develop and implement comprehensive in-flight emergency medical systems that ensure:

(a) rapid 24-hour access to qualified emergency medical personnel on the ground;

(b) at a minimum, voice communication with qualified ground-based emergency personnel;(c) written protocols, guidelines, algorithms, and procedures for responding to in-flight medical emergencies;

(d) efficient mechanisms for data collection, reporting, and surveillance, including development of a standardized incident report form;

(e) adequate medical supplies and equipment aboard aircraft;

(f) routine flight crew safety training;

(g) periodic assessment of system quality and effectiveness; and

(h) direct supervision by physicians with appropriate training in emergency and aerospace medicine.

H-45.979, "Air Travel Safety"

Our AMA: (1) encourages the ongoing efforts of the Federal Aviation Administration, the airline industry, the Aerospace Medical Association, the American College of Emergency Physicians, and other appropriate organizations to study and implement regulations and practices to meet the health needs of airline passengers and crews, with particular focus on the medical care and treatment of passengers during in-flight emergencies; (2) encourages physicians to inform themselves and their patients on the potential medical risks of air travel and how these risks can be prevented; and become knowledgeable of medical resources, supplies, and options that are available if asked to render assistance during an in-flight medical emergency; and (3) will support efforts to educate the flying physician public about in-flight medical emergencies (IFMEs) to help them participate more fully and effectively when an IFME occurs, and such educational course will be made available online as a webinar.

H-130.937, "Delivery of Health Care by Good Samaritans"

1. Our AMA will work with state medical societies to educate physicians about the Good Samaritan laws in their states and the extent of liability immunity for physicians when they act as Good Samaritans.

2. Our AMA encourages state medical societies in states without "Good Samaritan laws," which protect qualified medical personnel, to develop and support such legislation.

3. Where there is no conflict with state or local jurisdiction protocol, policy, or regulation on this topic, the AMA supports the following basic guidelines to apply in those instances where a bystander physician happens upon the scene of an emergency and desires to assist and render medical assistance. For the purpose of this policy, "bystander physicians" shall refer to those physicians rendering assistance voluntarily, in the absence of pre-existing patient-physician would not ordinarily respond to requests for emergency assistance. (a) Bystander physicians should recognize that prehospital EMS systems operate under the authority and direction of a licensed EMS physician, who has both ultimate medical and legal responsibility for the system. (b) A reasonable policy should be established whereby a bystander physician may assist in an emergency situation, while working within area-wide EMS protocols. Since EMS providers (non-physicians) are responsible for the patient, bystander physicians should work collaboratively, and not attempt to wrest control of the situation from EMS providers. (c) It is the obligation of the bystander physician

to provide reasonable self-identification. (d) Where voice communication with the medical oversight facility is available, and the EMS provider and the bystander physician are collaborating to provide care on the scene, both should interact with the local medical oversight authority, where practicable. (e) Where voice communication is not available, the bystander physician may sign appropriate documentation indicating that he/she will take responsibility for the patient(s), including provision of care during transportation to a medical facility. Medical oversight systems lacking voice communications capability should consider the addition of such communication linkages to further strengthen their potential in this area. (f) The bystander physician should avoid involvement in resuscitative measures that exceed his or her level of training or experience. (g) Except in extraordinary circumstances or where requested by the EMS providers, the bystander physician should refrain from providing medical oversight of EMS that results in deviation from existing EMS protocols and standing orders.

4. Our AMA urges the International Civil Aviation Organization to make explicit recommendations to its member countries for the enactment of regulations providing "Good Samaritan" relief for those rendering emergency medical assistance aboard air carriers and in the immediate vicinity of air carrier operations.

# REPORT OF THE BOARD OF TRUSTEES

B of T Report 29-A-18

Subject:Support for Service Animals, Emotional Support Animals, A and Medical Benefits of Pet Ownership (Resolution 508-A-2)		Support for Service Animals, Emotional Support Animals, Animals in Healthcare, and Medical Benefits of Pet Ownership (Resolution 508-A-17)	
	Presented by:	Gerald E. Harmon, MD, Chair	
	Referred to:	Reference Committee E (Douglas Martin, MD, Chair)	
1	INTRODUCT	ION	
2 3 4 5 6	At the 2017 Annual Meeting, Resolution 508-A-17, "Support for Service Animals, Emotional Support Animals, Animals in Healthcare, and Medical Benefits of Pet Ownership," introduced by the Medical Student Section and referred by the House of Delegates (HOD), asked:		
<ul> <li>That our AMA (1) recognize the potential medical benefits of animal-assisted therapy a animals as companions; and (2) encourage research into the use and implementation of animals, emotional support animals and animal-assisted therapy as both a therapeutic ar management technique of disorders and handicaps when expert opinion and the scientif literature show a potential benefit.</li> </ul>		MA (1) recognize the potential medical benefits of animal-assisted therapy and companions; and (2) encourage research into the use and implementation of service motional support animals and animal-assisted therapy as both a therapeutic and ent technique of disorders and handicaps when expert opinion and the scientific how a potential benefit.	
13 14 15 16 17	<ul> <li>Considerable confusion exists in differentiating service animals, emotional support animals</li> <li>(ESAs), and companion animals as well as the role of animals in animal-assisted therapy (AAT)</li> <li>This report will define the different categories of assistance animals and outline the current</li> <li>landscape of evidence related to the use of animals in medical treatments.</li> </ul>		
18	BACKGROUN	ND	
<ul> <li>Lack of clarity and confusion e</li> <li>animals used for emotional sup</li> <li>animals for a variety of reason</li> <li>communicate findings across t</li> </ul>		and confusion exist regarding the terms used to designate the function and role of or emotional support, comfort, and therapy. Individuals with disabilities may use variety of reasons, so a clear vocabulary is necessary to advance the science and findings across these disciplines. <sup>1</sup>	
25 26 27 28 29 30 31	Differentiating assistance that the animal required obedience whi service, militant specific public not the person	a factors in the categorization of animals include: 1) the animal's ability to provide is related to an individual's disability; 2) whether assistance or support provided by uires either a basic or advanced skill level (basic skills are synonymous with simple le advanced skills are more complex or specialized tasks); and 3) whether a public ry, or healthcare professional uses the animal to assist in the implementation of a service task or health-related treatment plan (the primary care-giver for the animal is with the disability).	

## 1 CATEGORIES OF ASSISTANCE ANIMALS

2 3

#### Service Animal

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5 As defined by Title II and Title III of the Americans with Disabilities Act (ADA), a service animal 6 is a dog (or in some circumstances, miniature horse) "that is individually trained to do work or 7 perform tasks for the benefit of an individual with a disability including a physical, sensory, 8 psychiatric, intellectual, or other mental disability."<sup>2</sup> The work or tasks performed by a service dog 9 must be directly related to the individual's disability and that individual is the primary handler and 10 care-giver of the animal. The ADA definition specifically excludes dogs whose sole function is to 11 provide comfort or emotional support. Service animals have broad access to public locations, but access may be prohibited when their presence results in changes to normal business practice or 12 when their presence poses health or safety risks.<sup>2</sup> These animals have an advanced level of training 13 and nationally-recognized certification programs are available but not mandated.<sup>1,3</sup> Service dogs 14 15 receive up to two years of training, and can cost more than \$40,000. Current demand exceeds 16 availability, and some individuals may wait for several years. The primary care-giver of the dog is 17 often required to live at a training center for a period of time to receive training as well. Guide 18 dogs, autism dogs, psychiatric service dogs, and diabetic alert dogs are examples of trained service 19 animals. Other species of animals, either domestic trained or untrained, are not considered service 20 animals. 21

During air travel, the Air Carrier Access Act protects the rights of passenger with disabilities and must permit a service animal to accompany a passenger with a disability. Identification cards, other written documentation, presence of harnesses, tags, or the credible verbal assurances of a qualified individual with a disability using the animal qualify as evidence that the animal is a service animal.<sup>4</sup>

- 27
- 28 Public Service or Military Animal
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Public service or military animals have been trained in advanced skills to provide work or tasks to
 assist public service or military professionals in performing their duties.<sup>1</sup> Cadaver dogs, search and-rescue dogs, and police dogs are examples of public service animals.

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34 Therapy Animals

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36 Therapy animals are trained in either basic or advanced skills to assist a healthcare professional qualified within the scope of a therapeutic treatment plan. These animals are used by professionals 37 38 for AAT to help their patients or clients achieve treatment goals. The therapy is conducted under 39 the guidance of a responsible healthcare professional and the treatment is conducted according to 40 accepted practices and ethical principles, which include adequate training of the professional to 41 work with the animal.<sup>1</sup> Therapy animals have limited access to public locations and are often under the care of the professional who oversees the AAT. The patient receiving the AAT is not the care-42 43 giver of the animal.

- 44
- 45 Visitation Animals
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47 Visitation animals are trained in basic skills to provide comfort and support to individuals through

48 companionship and social interaction primarily in nursing homes, hospitals, and schools.<sup>1</sup>

49 Visitation animals are not required to be accompanied by healthcare professionals and are usually

50 handled and owned by community volunteers.<sup>1</sup>

1 **Emotional Support Animals** 

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3 ESAs provide physical, psychiatric, or emotional support to individuals primarily in their home. No 4 standards exist for the training of ESAs, which usually have only basic obedience skills because 5 they are primarily owned pets.<sup>1,3</sup> ESA access to public locations is limited. Their rights are governed by the Fair Housing Act of 1988 (FHA) which states that ESAs can reside in both public 6 7 and private housing with proof of need for an ESA. Under Federal Department of Housing and 8 Urban Development regulations, an animal qualifies as a support animal if an individual has a 9 disability, an animal is needed to assist with a disability, and the individual demonstrates that there 10 is a relationship between the disability and the assistance that the animal provides.<sup>1</sup> Proof of need is most easily, and often, conveyed with a letter from a physician describing the necessity of an 11 12 animal to a person's specific disability. Of note and according to the ADA, a letter from a 13 physician stating the person has a disability and needs an animal for emotional support does not mean that animal qualifies as a service animal.<sup>2</sup> 14 16 According to federal regulations, airlines are not required to accept ESAs unless passengers

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17 provide current documentation on the letterhead of a licensed mental health professional (e.g., 18 psychiatrist, psychologist, licensed clinical social worker, including a medical doctor specifically 19 treating the passenger's mental or emotional disability) stating: 1) the passenger has a mental or 20 emotional disability recognized in the Diagnostic and Statistical Manual of Mental Disorders-21 Fourth Edition (DSM IV); 2) the passenger needs the ESA as an accommodation for air travel

22 and/or for activity at the passenger's destination; 3) the individual providing the assessment is a

23 licensed mental health professional, and the passenger is under his or her professional care; and 4) the date of the documentation and the mental health professional's license information.<sup>4</sup> 24

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No certification or registration standards exist for ESAs; however, many online agencies claim to 26 "register" an ESA for a fee, offer identification cards, kits with identification vests, and some provide healthcare professional letters for a fee.<sup>5-8</sup> The industry that has developed around the 27 28 29 certification of ESAs to allow pet owners to have their animals with them in restricted housing and 30 on flights at no cost has raised concerns from both professional and ethical standards perspectives.<sup>9</sup>

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#### 32 SERVICE ANIMAL AND EMOTIONAL SUPPORT ANIMAL POLICY

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34 The recent proliferation of service dogs and ESAs has led to individuals taking advantage of unclear policies and misrepresenting animals as service animals.<sup>3</sup> The ADA permits only two 35 36 questions to be asked of people with service animals: 1) Is the dog a service animal and 2) what 37 task is the dog trained to perform? No additional inquiry can be made regarding a disability, and no proof of service dog status can be requested. No federal licenses or documents to prove service dog 38 39 status exist, but some states do have "assistance animal" registries for service dogs with the 40 intended purpose of making access to public places easier for the animal and handler.<sup>10</sup> A recent study of assistance dog registrations in California revealed that registrations have increased sharply 41 in the past decade and that tags have been mistakenly issued to ESAs, some cats, and dogs not 42 43 fitting the definition of assistance dogs under the law.<sup>11</sup>

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Although there is substantial variation in scope and penalty, nineteen states have laws against the fraudulent representation of a service animal.<sup>12,13</sup> Other states are considering legislation against 45 46 fraudulent ESAs.<sup>13,14</sup> Furthermore, proposed federal legislation amending the Air Carrier Access 47 Act includes ESAs in the definition of service animals.<sup>15</sup> 48

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50 True service dogs are essential for the well-being of their human owners and both humans and the 51 service dogs are put at risk by untrained dogs in public places. Advocates for laws against service

1 dog fraud, as well as responsible pet owners, have voiced opinions that new legislation should

2 include public education efforts on legitimately trained service dogs and the distractions imposed

3 by untrained pets and the need for a national certification program and registry for legitimately

- 4 trained service dogs.<sup>13,16</sup>
- 5

Few studies have addressed the public health risks of animals in the healthcare setting and the
 limited research that has been conducted indicates cause for concern. For example, methicillin-

limited research that has been conducted indicates cause for concern. For example, methicillin resistant *Staphylococcus aureus* (MRSA) has increasingly been described in cats and dogs making

these animals a potential source of MRSA exposure in healthcare facilities.<sup>17</sup> In a survey of U.S.

10 hospitals, elder care facilities, and therapy animal organizations, health and safety policies for

11 therapy animals varied significantly and many did not follow recommended guidelines for animal

- 12 visitation, potentially compromising human and animal safety.<sup>18,19</sup>
- 13
- 14 15

EVIDENCE RELATED TO THE USE OF ANIMALS IN MEDICAL TREATMENTS

Limited evidence exists regarding the use of animals for treatments of individuals. Evidence of

17 benefits of AAT and animals as companions is limited in depth because the sample sizes of the few clinical trials are either too small to produce reliable results or there is little evidence that the 18 improvement is due to the presence of the animal as opposed to interacting with the animals' 19 20 sympathetic handlers. Additionally, study authors note the need for longitudinal follow-up studies 21 to verify the stability of a therapeutic effect attributed to the AAT on the patients. Of the limited 22 and relatively low quality randomized controlled trials identified, approximately half involved 23 "mental and behavioral disorders" and the types of animal interventions included dog, cat, dolphin, bird, cow, rabbit, ferret, and guinea pig.<sup>20-25</sup> Numerous examples of individual case studies and 24

- 25 individual clinical anecdotes exist in the literature.<sup>26</sup>
- 26

The American Veterinary Medical Association (AVMA) and others have researched the benefits of pet ownership and maintain resources detailing the work.<sup>27-29</sup> The Human-Animal Bond Research Initiative (HABRI) Foundation and the Purdue University College of Veterinary Medicine maintain an online platform for open research and collaboration regarding the relationships between humans and their pets.<sup>30</sup>

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33 CURRENT AMA POLICY

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35 AMA policy does not address the use of AAT or companion animals, but broadly addresses

36 alternative treatments. Current AMA Policy H-480.964, "Alternative Medicine," addresses

37 alternative therapies and states research should be done to evaluate efficacy; physicians should

38 routinely inquire and educate themselves and their patients about alternative therapies; and that

39 patients should be educated about any potential hazards of stopping conventional medical

40 treatment. Policy H-295.902, "Alternative Medicine," states that medical school courses addressing

41 alternative medicine should present the scientific view of unconventional therapies, potential

42 therapeutic utility, safety, and efficacy.

1	RECOMMENDATIONS		
2			
3	The Board of Trustees recommends the following policy be adopted in lieu of Resolution 508-A-		
4	17, and the remainder of the report be filed:		
5			
6	Service Animals, Animal-Assisted Therapy, and Animals in Healthcare		
7	Our American Medical Association:		
8	1.	Encourages research into the use of animal-assisted therapy as a part of a therapeutic	
9		treatment plan.	
10	2.	Supports public education efforts on legitimately trained service animals, as defined by the	
11		Americans with Disabilities Act (ADA).	
12	3.	Supports a national certification program and registry for legitimately trained service	
13		animals, as defined by the ADA.	
14	4.	Encourages health care facilities to set evidence-based policy guidelines for animal	
15		visitation. (New HOD Policy)	
	Fiscal Note: Less than \$500		

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# REPORT OF THE BOARD OF TRUSTEES

	Subject:	In-Flight Emergencies (Resolution 516-A-17, Resolve 5)		
	Presented by:	Gerald E. Harmon, MD, Chair		
	Referred to:	Reference Committee E (Douglas Martin, MD, Chair)		
1	INTRODUCTI	ION		
2 3 4 5	At the 2017 Ar introduced by t	nnual Meeting, Resolve 5 of Resolution 516-A-17, "In-Flight Emergencies," the Minority Affairs Section and referred by the House of Delegates (HOD), asked:		
6 7 8 9	That our American Medical Association (AMA) offer medical trainees and physicians medical education courses to prepare for addressing in-flight emergencies during its meetings and/or by strongly encouraging its affiliated state and local branches to offer similar education courses.			
<ul> <li>This report will outline the current options for physician continuing medical education (CM guidance, and policy on the topic of in-flight medical emergencies (IFMEs).</li> </ul>				
12 13 14	BACKGROUND			
15 16 17 18 19 20 21	IFMEs are defined as medical events that require the attention of medical professionals or the flight staff and crew aboard an aircraft. These emergency events occur in about one out of every 604 flights, but the actual incidence of these events is unknown and this is likely an underestimate because of underreporting. <sup>1</sup> The most common medical emergencies are feelings of lightheadedness and dizziness, acute infections, shortness of breath, trauma, syncope, altered mental status, stroke, and acute coronary syndromes. <sup>1</sup>			
21 22 23	ON-BOARD MEDICAL RESOURCES			
23 24 25 26 27 28 29 30 31	The Federal Aviation Administration (FAA) mandates that U.Sbased airlines carry first aid kits that are stocked with basic supplies such as bandages and splints. The requirements were arrived at based on public input during a Notice of Proposed Rulemaking included in the Aviation Medical Assistance Act of 1998. At least one kit must contain the required items, and at least one automated external defibrillator (AED) must be available. <sup>2</sup> For international airlines, medical supply requirements are determined by the corresponding national aviation regulatory authority in collaboration with the airlines they regulate.			
32 33 34 35 36 37	Ground-based haul aircraft, to based medical is trained in the particular opera of the aircraft,	medical support systems (GBMS) are widely used by airlines, especially by long o provide advice to crew who are dealing with a medical emergency. The ground officer can provide advice to crew and to an on board volunteer doctor since he/she e provision of aircraft related medical advice, knows exactly what is contained in a ator's on board medical supplies and is aware of the medical facilities in the vicinity should a diversion need to be considered.		

$\frac{1}{2}$	AIRLINE PROTOCOLS FOR MANAGING IN-FLIGHT MEDICAL EVENTS
2 3 4 5 6 7 8 9	When in an aircraft, the pilot, assisted by the co-pilot, has overall responsibility for the passengers, the crew, the flight, and the aircraft. Cabin crews, who are responsible for managing IFMEs are trained to recognize common medical issues and provide first aid and basic cardiopulmonary resuscitation. Cabin crew will generally make an initial assessment of a passenger in need of medical assistance and will keep the pilot informed about the situation. Crew is also responsible for requesting assistance from any onboard medical professionals if needed. The pilot can call GBMS for assistance if necessary. <sup>3</sup>
10 11	IFME GUIDANCE, TRAINING, AND POLICY
12 13 14 15 16 17 18 19	Congress passed the Aviation Medical Assistance Act in 1998, which protects providers who respond to IFMEs. <sup>4</sup> Onboard emergency medical equipment, including automated external defibrillators (AEDs) and emergency medical kits are federally regulated; minimum emergency medical kit requirements exist and AEDs are required on all airplanes of air carriers operating under CFR part 121 with a maximum payload capacity of more than 7,500 pounds and with at least one flight attendant. <sup>5,6</sup>
20 21 22 23 24 25 26 27 28 29 30 31 32 23	The Aerospace Medical Association (AsMA) has done extensive work to address IFMEs. <sup>7</sup> With the collaboration of other medical organizations, including the AMA, AsMA released a guidance document with information and/or recommendations about what the most common IFMEs are, how often they occur, necessary on-board medical supplies, appropriate cabin crew training, the need for automated external defibrillators, and legal aspects of IFMEs. In April 2016, AsMA convened an Aircraft Emergency Medical Kits Workgroup that included AMA representation. Based on the outcome of this meeting, AsMA further refined its recommendations regarding medical guidelines for airline travel/in-flight medical care, including the contents of on-board medical supply kits. These recommendations support an expanded cache of supplies compared with those required by the FAA. <sup>8</sup> The AsMA guidance also includes information to assist volunteer medical professionals who respond to a request for medical assistance, including advice on providing identification and proof of credentialing, inquiring about ground support, and documenting diagnostic findings and treatment.
<ul> <li>33</li> <li>34</li> <li>35</li> <li>36</li> <li>37</li> <li>38</li> <li>39</li> </ul>	In collaboration with the AMA, International Civil Aviation Organization (ICAO), International Air Transport Association (IATA), International Academy of Aviation and Space Medicine (IAASM), American Osteopathic Association (AOA), and American College of Emergency Physicians (ACEP), AsMA also has developed an educational and training resource document for health professionals entitled, "Managing In-flight Medical Events,". <sup>9</sup>
40 41 42 43 44 45 46 47	Other aviation organizations also regularly study, make recommendations on, and have informational material related to IFMEs. IATA publishes a medical manual which details protocols for IFMEs. <sup>10,11</sup> ICAO works in close collaboration with agencies and organizations including the World Health Organization (WHO), IATA, and Airport Council International (ACI) to provide medically related publications, training, and policy. ICAO also cooperates and consults with the chief medical officers of civil aviation authorities around the world and the Medical Directors of airline companies. <sup>12</sup>
48	Recently, a CME opportunity on the topic of IFMEs was published in the <i>Cleveland Clinic Journal</i>

49 of Medicine.<sup>1</sup>

1	CURRENT AMA POLICY			
2	Extensive AMA policies address IEMEs Policy H_15 979 "Air Travel Safety" (Appendix)			
4	supports afforts to aducate the flying physician public about IEMEs to halp them participate more			
т 5	fully and effectively when an IFME occurs. Policy H-45 978 "In-flight Medical Emergencies."			
6	discusses in-flight emergency medical supplies and equipment and H-45 982 "Improvement in			
7	U.S. Airlines Aircraft Emergency Kits." urges the FAA to work with the airline industry and			
8	appropriate medical specialty societies to periodically review data on the incidence and outcomes			
9	of in-flight medical emergencies and issue recommendations regarding the contents of in-flight			
10	medical kits and the use of emergency lifesaving devices.			
11				
12	SUMMARY AND CONCLUSION			
13				
14	Although numerous publications of experiences managing IFMEs exist in the literature, many are			
15	anecdotal, based on one event, and may draw conclusions that are not necessarily applicable			
16	throughout the industry. AsMA, in collaboration with several other organizations, has developed			
1/ 10	guidance and training for medical practitioners who volunteer to provide assistance on board an			
18	aircraft. Additionally, other resources are available to physicians interested in learning more about			
19 20	$A_{\rm S}MA_{\rm guidance}$ document <sup>9</sup>			
20	<ul> <li>ASMA guidance document</li> <li>IATA medical manual<sup>11</sup></li> </ul>			
21	<ul> <li>Cleveland Clinic Journal of Medicine CMF<sup>13</sup></li> </ul>			
23	• In-Flight Medical Emergencies during Commercial Travel New England Journal of			
24	<i>Medicine</i> article detailing response recommendations, consulting with GBMS, and medical			
25	kit contents <sup>2</sup>			
26	• ICAO information regarding Aviation Medicine <sup>12</sup>			
27	• Handling In-Flight Medical Emergencies <sup>14</sup>			
28	• What to do during inflight medical emergencies? Practice pointers from a medical ethicist			
29	and an aviation medicine specialist. <sup>3</sup>			
30	• FAQ: What Should Happen During an Inflight Medical Emergency <sup>15</sup>			
31				
32	Given that up-to-date educational resources are available on this topic, the Board of Trustees			
33	believes further efforts on this topic by our AMA are not necessary at this time. The extensive			
34 25	work by ASMA and others, as well as current AMA policy, address IFMEs in depth.			
33 26				
30 37	KEUUMIMENDAHUN			
38	The Board of Trustees recommends the existing AMA Policy H-45 979 "Air Travel Safety" be			
30	reaffirmed in lieu of Resolve 5. Resolution 516-A-17 and the remainder of the report be filed			
	The second of the report of the second of th			

40 (Reaffirm Current HOD Policy)

Fiscal Note: Less than \$500

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## APPENDIX

Policy for Reaffirmation

H-45.979, "Air Travel Safety"

#### Our AMA:

- (1) encourages the ongoing efforts of the Federal Aviation Administration, the airline industry, the Aerospace Medical Association, the American College of Emergency Physicians, and other appropriate organizations to study and implement regulations and practices to meet the health needs of airline passengers and crews, with particular focus on the medical care and treatment of passengers during in-flight emergencies;
- (2) encourages physicians to inform themselves and their patients on the potential medical risks of air travel and how these risks can be prevented; and become knowledgeable of medical resources, supplies, and options that are available if asked to render assistance during an in-flight medical emergency; and
- (3) will support efforts to educate the flying physician public about in-flight medical emergencies (IFMEs) to help them participate more fully and effectively when an IFME occurs, and such educational course will be made available online as a webinar.

# REPORT OF THE BOARD OF TRUSTEES

	Subject:	Timely Referral to Pain Management Specialist (Resolution 714-A-17)		
	Presented by:	Gerald E. Harmon, MD, Chair		
1	Referred to:	Reference Committee E (Douglas Martin, MD, Chair)		
	INTRODUCTION			
2 3 4 5	At the 2017 Annual Meeting, the House of Delegates (HOD) referred Resolution 714-A-17, "Timely Referral to Pain Management Specialist," for report back at the 2018 Annual Meeting. This resolution was introduced by the Michigan Delegation and asked that:			
6 7 8 9 10 11 12 13 14 15 16 17	Our American Medical Association (AMA) urge the Centers for Medicare & Medicaid Services (CMS) and the Medicare Contractor Advisory Committee to endorse and adopt evidence-based clinical practice guidelines on the management and treatment of pain including but not limited to timely and appropriate referral to pain management specialists.			
	During the hearing on this resolution, Reference Committee G heard mixed testimony. The majority of testimony on Resolution 714 opposed mandating that physicians should refer patients to pain management specialists. Testimony also noted the lack of access to pain management specialists in many communities, in addition to long waiting times to see pain specialists, making timely referrals to see these specialists problematic. This report discusses whether the AMA should urge CMS to adopt clinical practice guidelines on the management and treatment of pain.			
10 19 20	BACKGROUN	ACKGROUND		
20 21 22	Existing AMA Policies			
23 24 25 26 27 28	The AMA currently has numerous policies on pain management, including Policies H-185.931, "Coverage for Chronic Pain Management," H-410.958, "Interventional Pain Management: Advancing Advocacy to Protect Patients from Treatment by Unqualified Providers," H-410.950, "Pain Management," D-120.976, "Pain Management," and D-160.981, "Promotion of Better Pain Care."			
29 30 31 32	These policies in full range of ev AMA's support providing physi	These policies note AMA's support for health insurance coverage that gives patients access to the full range of evidence-based chronic pain management. In addition, existing policies state the AMA's support for efforts to expand the capacity of practitioners and programs capable of providing physician-led interdisciplinary pain management services.		
34 35 36	Furthermore, expain manageme MDs and DOs i	kisting AMA policy states that the AMA "will work to ensure that interventional ent is the practice of medicine and the treatment rendered to patients by qualified is directed by best evidence," Policy H-410.958. There is further existing AMA		

1 policy which states that the AMA "will support more effective promotion and dissemination of 2 educational materials for physicians on prescribing for pain management," Policy D120.976.

3 4

Existing Clinical Practice Guidelines

5 6

7

8

Numerous clinical practice guidelines exist on the management and treatment of pain, including from the American Academy of Pain Medicine, the American Pain Society, the American College of Emergency Physicians, and American College of Physicians.<sup>1</sup>

- 9 10 DISCUSSION
- 11
- 12 Clinical Practice Guidelines Developed by Specialties
- 13

Resolution 714-A-17 asks the AMA to urge CMS to endorse and adopt evidence-based clinical practice guidelines. However, to do so would be generally inconsistent with current AMA policy. The AMA has historically supported the development of clinical practice guidelines from specialty societies as opposed to CMS or other federal government entities. We believe that specialty societies are better positioned to consult with an array of physicians within a given specialty, and that physicians, rather than CMS, should take the lead on the development of clinical practice guidelines.

20 21

In addition, numerous clinical practice guidelines already exist from specialty societies whose physicians handle the management and treatment of pain, including the American Academy of Pain Medicine, the American Pain Society, and the American College of Emergency Physicians. If a physician wishes to refer to clinical practice guidelines on managing and treating pain, there are numerous existing guidelines to consult.

27

28 Referral to Pain Management Specialist

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Resolution 714-A-17 would call on the federal government to set a standard that physicians should refer patients to pain management specialists. However, AMA policy recognizes that it is not always necessary for patients with pain to be referred to a pain management specialist. In addition, many communities do not have access to pain management specialists or have long waiting times to see pain management specialists, making timely referrals to see these specialists problematic.

35

36 Modification of Existing AMA Policy

37

The adoption of Resolution 714-A-17 would not be consistent with the plethora of existing AMA policy for the reasons stated above. However, the Board of Trustees believes that existing AMA policy should be amended to state more succinctly the AMA's support for efforts to improve the quality of care for patients with pain, ensuring access to multiple analgesic strategies, with a focus on achieving improvement in function and activities of daily living. Existing policy should also be amended to document the AMA's position that guidance on pain management should be developed by the specialties who manage these conditions.

1 2	RECOMMENDATION		
3 4 5	The Board of Trustees recommends that Policy H-185.931 be amended by addition and deletion i lieu of Resolution 714-A-17 and the remainder of the report be filed:		
5 6 7	Policy H-185.931, "Coverage for Chronic Pain Management"		
8 9 10 11 12	1. <u>Our American Medical Association (AMA) supports efforts to in</u> patients with pain, ensuring access to multiple analgesic strategies options when appropriate, with a focus on achieving improvement daily living.	nprove the quality of care for es, including non-opioid nt in function and activities of	
13 14 15 16 17	2. <u>Guidance on pain management for different clinical indications s</u> <u>specialties who manage those conditions and disseminated the sa</u> <u>guidelines are promoted, such as through medical journals, medical</u> <u>appropriate outlets</u> .	should be developed by the time way other clinical cal societies, and other	
18 19 20 21 22	1 <u>3</u> . Our American Medical Association (AMA) will advocate for an comprehensive, multidisciplinary pain management approaches t assess co-occurring mental health or substance use conditions, ar the interdependency of treatment methods in addressing chronic	increased focus on that include the ability to re physician led, and recognize pain.	
23 24 25 26	2 <u>4</u> . Our AMA supports health insurance coverage that gives patients evidence-based <del>chronic</del> pain management modalities, and that co equivalent to coverage provided for medical or surgical benefits.	access to the full range of overage for these services be	
27 28 29 30 31	3 5. Our AMA supports efforts to expand the capacity of practitioners providing physician-led interdisciplinary pain management servi address the physical, psychological, and medical aspects of the p presentation and involve patients and their caregivers in the decis (Modify Current HOD Policy)	s and programs capable of ces, which have the ability to atient's condition and sion-making process.	

Fiscal Note: Less than \$500.

#### REFERENCES

<sup>1</sup> For example, see American College of Emergency Physicians, *Optimizing the Treatment of Acute Pain in the Emergency Department*, at

https://www.acep.org/Search.aspx?filter=acep&searchtext=pain%20&folderpath=ACEP/Clinical%20and%2 OPractice%20Management/policy%20statements/#sm.0001rldrr218n6d0tq65ngn5ovuzv; American Pain Society, *Clinical Practice Guidelines*, at <u>http://americanpainsociety.org/education/guidelines/overview</u>; the American Academy of Pain Medicine, For the Primary Care Provider: When to Refer to a Pain Specialist, at <u>http://www.painmed.org/files/when-to-refer-a-pain-specialist.pdf</u>; and American College of Physicians, Noninvasive Treatments for Acute, Subacute, and Chronic Low Back Pain: A Clinical Practice Guideline From the American College of Physicians, at <u>https://www.ncbi.nlm.nih.gov/pubmed/28192789</u>.

#### APPENDIX - CURRENT AMA POLICY

#### Policy H-185.931, "Coverage for Chronic Pain Management"

1. Our American Medical Association will advocate for an increased focus on comprehensive, multidisciplinary pain management approaches that include the ability to assess co-occurring mental health or substance use conditions, are physician led, and recognize the interdependency of treatment methods in addressing chronic pain.

2. Our AMA supports health insurance coverage that gives patients access to the full range of evidence-based chronic pain management modalities, and that coverage for these services be equivalent to coverage provided for medical or surgical benefits.

3. Our AMA supports efforts to expand the capacity of practitioners and programs capable of providing physician-led interdisciplinary pain management services, which have the ability to address the physical, psychological, and medical aspects of the patient's condition and presentation and involve patients and their caregivers in the decision-making process.

# Policy H-410.958, "Interventional Pain Management: Advancing Advocacy to Protect Patients from Treatment by Unqualified Providers"

Our AMA: (1) encourages and supports state medical boards and state medical societies in adopting advisory opinions and advancing legislation, respectively, that interventional pain management of patients suffering from chronic pain constitutes the practice of medicine; and (2) will work to ensure that interventional pain management is the practice of medicine and the treatment rendered to patients by qualified MDs and DOs is directed by best evidence. Further, our AMA will collect, synthesize and disseminate information regarding the educational programs in pain management and palliative care offered by nursing programs and medical schools in order to demonstrate adherence to current standards in pain management.

#### Policy H-410.950, "Pain Management"

Our AMA adopts the following guidelines on Invasive Pain Management Procedures for the Treatment of Chronic Pain, Including Procedures Using Fluoroscopy:

Interventional chronic pain management means the diagnosis and treatment of pain-related disorders with the application of interventional techniques in managing sub-acute, chronic, persistent, and intractable pain. The practice of pain management includes comprehensive assessment of the patient, diagnosis of the cause of the patient's pain, evaluation of alternative treatment options, selection of appropriate treatment options, termination of prescribed treatment options when appropriate, follow-up care, the diagnosis and management of complications, and collaboration with other health care providers.

Invasive pain management procedures include interventions throughout the course of diagnosing or treating pain which is chronic, persistent and intractable, or occurs outside of a surgical, obstetrical, or post- operative course of care. Invasive pain management techniques include:

1. ablation of targeted nerves;

2. procedures involving any portion of the spine, spinal cord, sympathetic nerves or block of major peripheral nerves, including percutaneous precision needle placement within the spinal column with placement of drugs such as local anesthetics, steroids, and analgesics, in the spinal column under fluoroscopic guidance or any other radiographic or imaging modality; and 3. surgical techniques, such as laser or endoscopic diskectomy, or placement of intrathecal infusion pumps, and/or spinal cord stimulators.

At present, invasive pain management procedures do not include major joint injections (except sacroiliac injections), soft tissue injections or epidurals for surgical anesthesia or labor analgesia. When used for interventional pain management purposes such invasive pain management procedures do not consist solely of administration of anesthesia; rather, they are interactive procedures in which the physician is called upon to make continuing adjustments based on medical inference and judgments. In such instances, it is not the procedure itself, but the purpose and manner in which such procedures are utilized, that demand the ongoing application of direct and immediate medical judgment. These procedures are therefore within the practice of medicine, and should be performed only by physicians with appropriate training and credentialing. Invasive pain management procedures require physician-level training. However, certain technical aspects of invasive pain management procedures may be delegated to appropriately trained. licensed or certified, credentialed non-physicians under direct and/or personal supervision of a physician who possesses appropriate training and privileges in the performance of the procedure being supervised, and in compliance with local, state, and federal regulations. Invasive pain management procedures employing radiologic imaging are within the practice of medicine and should be performed only by physicians with appropriate training and credentialing.

#### Policy D-120.976, "Pain Management"

Our AMA will: (1) support more effective promotion and dissemination of educational materials for physicians on prescribing for pain management; (2) take a leadership role in resolving conflicting state and federal agencies' expectations in regard to physician responsibility in pain management; (3) coordinate its initiatives with those state medical associations and national medical specialty societies that already have already established pain management guidelines; and (4) disseminate Council on Science and Public Health Report 5 (A-06), "Neuropathic Pain," to physicians, patients, payers, legislators, and regulators to increase their understanding of issues surrounding the diagnosis and management of maldynia (neuropathic pain); and (5) disseminate Council on Science and Public Health Report 5 (A-10), "Maldynia: Pathophysiology and Nonpharmacologic Approaches," to physicians, patients, payers, legislators, and regulators to increase their understanding of issues surrounding the diagnosis and management of maldynia (neuropathic pain); and regulators to increase their understanding of issues surrounding the diagnosis (Approaches," to physicians, patients, payers, legislators, and regulators to increase their understanding of issues surrounding the diagnosis and management of maldynia (neuropathic pain).

#### Policy D-160.981, "Promotion of Better Pain Care"

1. Our AMA: (a) will express its strong commitment to better access and delivery of quality pain care through the promotion of enhanced research, education and clinical practice in the field of pain medicine; and (b) encourages relevant specialties to collaborate in studying the following: (i) the scope of practice and body of knowledge encompassed by the field of pain medicine; (ii) the adequacy of undergraduate, graduate and post graduate education in the principles and practice of the field of pain medicine, considering the current and anticipated medical need for the delivery of quality pain care; (ii) appropriate training and credentialing criteria for this multidisciplinary field of medical practice; and (iv) convening a meeting of interested parties to review all pertinent matters scientific and socioeconomic.

2. Our AMA encourages relevant stakeholders to research the overall effects of opioid production cuts.

3. Our AMA strongly urges the US Drug Enforcement Administration to base any future reductions in aggregate production quotas for opioids on actual data from multiple sources, including prescribing data, and to proactively monitor opioid quotas and supply to prevent any shortages that might develop and to take immediate action to correct any shortages.

4. Our AMA encourages the US Drug Enforcement Administration to be more transparent when developing medication production guidelines.

5. Our AMA and the physician community reaffirm their commitment to delivering compassionate and ethical pain management, promoting safe opioid prescribing, reducing opioid-related harm and the diversion of controlled substances, improving access to treatment for substance use disorders, and fostering a public health based-approach to addressing opioid-related morbidity and mortality.

#### EXECUTIVE SUMMARY

<u>Objective</u>. This report updates information on drug shortages since the 2017 report was developed, specifically commenting on the increase in drug shortages due to hurricanes that have impacted the pharmaceutical industry in Puerto Rico as well as other relevant policy considerations regarding manufacturer processes recently brought to light which have implications for the United States health care system.

<u>Methods</u>. English-language reports were selected from a PubMed and Google Scholar search from September 2016 to February 2018, using the text term "drug shortages" combined with "impact," "crisis," "oncology," "chemotherapy," "antibacterial," "pediatric(s)," "nutrition," and "parenteral." Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the US Food and Drug Administration (FDA), American Society of Health-System Pharmacists (ASHP), Pew Charitable Trusts, the Association for Accessible Medicines, the Pharmaceutical and Research Manufacturers of America (PhRMA), the Institute for Safe Medication Practices (ISMP), and by direct contact with key FDA, ASHP, and Utah Drug Information Service staff who monitor drug shortages and related issues on a daily basis. A recent roundtable report developed by ASHP also was consulted as a key resource.

<u>Results</u>. Drug shortages remain an ongoing public health concern in the United States and the FDA and ASHP continue to provide information regarding the topic. Although the rate of new shortages has decreased, long-term active and ongoing shortages are not resolving and critical shortages are impacting patient care and pharmacy operations. In late 2017, major hurricanes struck Puerto Rico which houses significant infrastructure for manufacturing critical pharmaceutical and other medical products. The FDA has issued multiple statements regarding the situation in Puerto Rico and has undertaken extensive efforts to avoid exacerbating critical drug shortages. In November 2017, AMA took part in an ASHP-convened meeting to review and identify new opportunities to address ongoing supply chain and patient-care challenges associated with drug product shortages. Eleven recommendations were crafted as a result of discussions at the roundtable.

<u>Conclusion</u>. Although recent natural disasters have increased the number of drug shortages only slightly, shortages of basic products such as saline and small-volume parenteral solutions, and their containers, are significantly impacting the health care system by affecting patient care, increasing the potential for drug errors, and influencing the manner in which health care teams function. Information and discussion at an ASHP-convened roundtable on current issues regarding drug shortages illuminated additional relevant policy considerations such as manufacturer transparency regarding production location and the cause(s) of shortages; quality of outsourcer compounding facilities; and the potential inclusion of vital drug manufacturing sites as critical infrastructure.

#### REPORT OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

CSAPH Report 2-A-18

Subject: Drug Shortages: Update

Presented by: Robert A. Gilchick, MD, Chair

Referred to: Reference Committee E (Douglas Martin, MD, Chair)

1 INTRODUCTION

American Medical Association (AMA) Policy H-100.956, "National Drug Shortages," directs the Council on Science and Public Health (CSAPH) to continue to evaluate the drug shortage issue and report back at least annually to the House of Delegates (HOD) on progress made in addressing drug shortages in the United States. This report provides an update on continuing trends in national drug shortages and ongoing efforts to further evaluate and address this critical public health issue.

- 9 METHODS
- 10

11 English-language reports were selected from a PubMed and Google Scholar search from 12 September 2016 to February 2018, using the text term "drug shortages" combined with "impact," "crisis," "oncology," "chemotherapy," "antibacterial," "pediatric(s)," "nutrition," and "parenteral." 13 Additional articles were identified by manual review of the references cited in these publications. 14 15 Further information was obtained from the Internet sites of the US Food and Drug Administration 16 (FDA), American Society of Health-System Pharmacists (ASHP), Pew Charitable Trusts, the Association for Accessible Medicines, the Pharmaceutical and Research Manufacturers of America 17 18 (PhRMA), the Institute for Safe Medication Practices (ISMP), and by direct contact with key FDA, 19 ASHP, and Utah Drug Information Service staff who monitor drug shortages and related issues on 20 a daily basis. A recent roundtable report developed by ASHP also was consulted as a key resource.<sup>1</sup> 21 22 BACKGROUND 23 The CSAPH has issued eight reports on drug shortages.<sup>2-9</sup> The findings and conclusions of the first 24 five reports are summarized in CSAPH Report 2-I-15, "National Drug Shortages: Update."<sup>7</sup> The 25 remainder of this report will update information on drug shortages since the 2017 report was 26

developed, specifically commenting on the increase in drug shortages due to hurricanes that have
 impacted the pharmaceutical industry in Puerto Rico as well as other relevant policy considerations

regarding manufacturer processes recently brought to light which have implications for the UnitedStates health care system.

31

# 32 CURRENT TRENDS IN DRUG SHORTAGES

33

34 Drug shortages remain an ongoing public health concern in the United States. Although the rate of 35 new shortages has decreased, long-term active and ongoing shortages are not resolving and critical

shortages are impacting patient care and pharmacy operations. Several commonly used products

required for patient care are in shortage including sterile infusion solutions (e.g., saline, amino 1

- acids, dextrose), as well as diazepam, lidocaine, hydromorphone, and morphine.<sup>10-12</sup> 2
- 3 4

Ongoing supply challenges of certain medications, typically injectable products that are off-patent 5 and have few suppliers, persist. Causes of these shortages continue to remain largely unchanged and are mostly triggered by quality problems during manufacturing processes.

6 7

8 As noted in previous Council reports, the two primary data sources for information on drug

9 shortages in the United States continue to be the Drug Shortage Program at the FDA and the Drug

10 Shortage Resource Center maintained by ASHP in cooperation with the University of Utah Drug

11 Information Service. According to the most recent data compiled by ASHP and the University of

12 Utah Drug Information Service, the total number of new shortages in 2017 was 146 (compared 13 with 154 in 2016) and the number of active shortages was 183 in quarter four of 2017. As of the

14 end of 2017, the largest number of shortages belongs to the class of electrolytes, nutrition, and

15 fluids; for 3% of the shortages, the reported reason was "natural disaster" (Appendix). The most

recent metrics reported by the FDA are listed in the 2017 Drug Shortages: Update report.<sup>9</sup> Updated 16 17 metrics from the FDA are anticipated in summer of 2018.

18

19 The FDA continues to utilize a mobile app to provide up-to-date access to drugs in shortage as well 20 as notifications about new and resolved drug shortages and ability for physicians to report a drug 21 shortage (Box 1). The ASHP drug shortage resource center provides a list of shortages and some 22 guidance on managing critical shortages (Box 1).

23

#### 24 STATE OF THE INDUSTRY

25

26 The U.S. Government Accountability Office (GAO) examined shortages of sterile injectable anti-27 infective and cardiovascular drugs in 2012, 2013, and 2014 and noted that the shortages were

- 28 strongly associated with three factors: 29
  - 1. A decline in the number of suppliers
- 30 2. Failure of at least one establishment making a drug to comply with manufacturing 31 standards resulting in a warning letter 32
  - 3. Drugs with sales of a generic version

33 These factors suggest that shortages may be triggered by supply disruptions and by market forces 34 in which there are low profit margins for generic drugs, resulting in manufacturers being less likely to increase production.<sup>1</sup> 35

36

37 Legislation enacted in 2012, the Food and Drug Administration Safety and Innovation Act (Title X: 38 Drug Shortages) (FDASIA) requires drug manufacturers to notify the U.S. Food and Drug 39 Administration (FDA) "of any change in production that is reasonably likely to lead to reduction in 40 supply" of a covered drug in the United States. Although this warning requirement has played a 41 significant role in reducing the number of drug shortages, it has not solved the problem.<sup>13</sup>

42

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

44

45 In late 2017, major hurricanes struck Puerto Rico which houses significant infrastructure for

46 manufacturing critical pharmaceutical and other medical products for worldwide distribution,

47 including the United States. The FDA has issued multiple statements regarding the manufacturing

48 situation in Puerto Rico. Extensive efforts have been undertaken to avoid exacerbating critical drug

49 shortages and addressing challenges related to refrigeration, storage and transportation. FDA also

50 has been working to relocate production in coordination with federal and local government

51 colleagues and pharmaceutical companies. Additionally, the agency is paying particularly close 1 attention to the demand for empty containers, which are also produced on the island, as an

- 2 alternative to filled infusion bags.<sup>14,15</sup>
- 3

4 A primary concern is the shortage of small-volume parenteral solution (SVP) products, including

5 saline, due to production and supply-chain problems on the island. ASHP and the University of

6 Utah Drug Information Service have developed a clinical resource on the conservation and

7 management of SVPs (Box 1).<sup>16</sup> Additionally, emergency physicians from Brigham and Women's

8 Hospital recently published an oral rehydration protocol for use to conserve sterile infusion fluids.<sup>17</sup>

9

# 10 ASHP DRUG SHORTAGES ROUNDTABLE

11

In November 2017, AMA took part in an ASHP-convened meeting to review and identify new opportunities to address ongoing supply chain and patient-care challenges associated with drug product shortages. The meeting served as a forum for several health care organizations to examine how FDASIA has impacted shortages and to address whether a need exists to build on the law with new recommendations.

17

18 FDA Drug Shortage Program Update

19

20 An update provided by staff from the FDA Drug Shortage Program confirmed that the notification 21 requirement enacted as part of FDASIA is generally being followed and that most companies 22 report to the agency when they anticipate or experience problems that may lead to a shortage. A 23 few companies have failed to comply with reporting requirements suggesting the need for 24 additional manufacturer education regarding their reporting responsibility. Timely notification 25 enables the FDA to create solutions intended to prevent the onset of a shortage (e.g., work with other manufacturers behind the scenes to ramp up production, expedite the review of an 26 27 abbreviated new drug application (ANDA) from another company, develop a work around for the 28 production issue, or begin the process of controlled importation of a drug to meet demand). FDA 29 staff reiterated that the requirement for manufactures to notify the FDA does not obligate them to 30 disclose the problem for the interruption, its expected duration, or an estimated time frame for 31 resolution. Additionally, under current US law, the agency cannot require a company to 32 manufacture a drug, no matter how critical or life-sustaining it is.

33

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

37

38 Outsourcer Compounding Facilities

39

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

45

47 Several issues were discussed at the roundtable regarding 503B facilities and their ability to

48 provide specific formulations in the event of drug shortages. It can take up to six weeks for 503B

49 facilities to increase or begin production of a drug in shortage and they can do so only after the

50 FDA adds the product to the shortage list. Because the products in short supply and the duration of

51 the shortage cannot be predicted, not only can delays exist in initiating production, but inconsistent
1 fulfillment from 503B facilities is common. Additionally, many 503B facilities are not able to

2 produce drugs from active pharmaceutical ingredients (APIs) and only repackage other

3 commercially available formulations. Adding to this complication, 503B facilities currently cannot

4 repackage SVPs because the empty bags needed to do so are also in shortage.

5

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

13

## 14 Drug Manufacturing as Critical Infrastructure

15

The term "critical infrastructure" is defined in the USA Patriot Act of 2001 as "systems and assets, 16 17 whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on security, national economic security, 18 national public health or safety, or any combination of those matters."<sup>19</sup> Flowing out of Presidential 19 Policy Directive 21 (PPD-21), titled Critical Infrastructure Security and Resilience, was the 20 drafting of an update to the National Infrastructure Protection Plan (NIPP), published by the 21 22 Department of Homeland Security (DHS). This update, titled NIPP: 2013, describes a national 23 effort to identify and achieve critical infrastructure security and resilience and manage risk through partnership efforts and information sharing between public and private organizations.<sup>20</sup> Because the 24 25 United States critical infrastructure is largely owned by the private sector, managing risk to enhance security and resilience needs to be a shared priority for industry and government. The 26 Healthcare and Public Health (HPH) Sector-Specific Plan (SSP) tailors the strategic guidance 27 provided in the NIPP to the unique operating conditions and risk landscape of the HPH sector.<sup>21</sup> 28 29 The HPH SSP outlines how public and private sector partners will evaluate risks; coordinate plans 30 and policy; and provide guidance to prevent, protect, mitigate, respond to, and recover from all 31 hazards that pose a threat to the HPH sector critical infrastructure. 32 33 At the roundtable, the Office of the Assistant Secretary for Preparedness and Response (ASPR), 34 Office of Emergency Management, part of the U.S. Department of Health & Human Services (DHHS), outlined its efforts to coordinate with DHS and public and private sector organizations 35 36 involved in disaster response. The DHS list of critical infrastructure, which includes the HPH sector, and criteria for determining the vulnerability of the infrastructure, may be re-examined in 37 38 the near future; the current plan has very specific parameters and few are HPH-related. 39

40 The discussion with ASPR focused on the potential for evaluating manufacturer locations and their 41 cybersecurity as criteria for determining risk and inclusion within the list of critical infrastructure. 42 The fact that several manufacturers were impacted by cyber events over the past year and that 43 product shortages were worsened by the recent hurricanes impacting Puerto Rico, highlight the 44 need to evaluate risk and hazard and disaster response for drug and medical product manufacturing. 45 However, production location for specific drugs and other medical products is proprietary 46 information and many manufacturers are unwilling to share this with DHHS and/or DHS. ASPR 47 wants to work more closely with manufacturers and explain the benefits of information sharing and 48 being included as critical infrastructure. Of note is that any information shared with DHS or DHHS 49 is, by law, protected from public disclosure and used only in the context of preparedness planning 50 and response. Additionally, DHHS in collaboration with DHS can provide analytical tools to help

manufacturers prepare for disasters, identify their dependencies such as power and water, and
 become more resilient.

- 3 4
- Automation Difficulties
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Many of the drugs currently in shortage are basic products required for patient care in all medical settings, such as saline and SVPs. Shortages of these basic products, and their containers, are significantly affecting patient care and healthcare providers because options to address these shortages are limited or risky.

9 10

11 Increasing automation and the use of informatics in hospitals and large healthcare centers has 12 created efficiencies, but the use of devices such as infusion pumps and the utilization of electronic 13 health records (EHRs) can be associated with problems in the case of drug shortages. Many devices 14 are often designed to use specific products from specific manufacturers. When the required product 15 is not available and alternatives must be used, it is burdensome and requires significant work to change parameters for device functionality, if it is possible at all. Many EHRs have specific drugs 16 17 and doses prepopulated for streamlining patient care and care team collaboration. When shortages 18 occur and other drugs or doses are the only options available. EHRs must be reprogrammed with the new options, often at each EHR station and for each patient individually. 19

20

21 *Recommendations Resulting from the Roundtable* 

22

Eleven recommendations were crafted as a result of discussions at the roundtable (Box 2). Some of
 them are already reflected in current AMA policy on drug shortages including urging

25 manufacturers to establish contingency plans or redundancies in production and requiring FTC

26 review of manufacturer mergers to evaluate shortage risk. Other recommendations include a call

27 for greater manufacturer transparency, more information on the quality of outsourcing

compounding facilities, and the examination of drug shortages as a national security initiative resulting in the addition of vital manufacturing sites as critical infrastructure.

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31 IMPACT OF SHORTAGES ON HEALTH CARE PRACTICE

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33 ISMP Practices Survey

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ISMP recently published the results of a drug shortage survey they conducted in late 2017, before
 natural disasters exacerbated the shortage problem.<sup>22</sup> Almost all respondents of the survey

37 practiced in a hospital setting. Shortages were reported across all treatment categories.

- Approximately 55% of respondents indicated experiencing shortages involving more than 20 drugs within the last six months and most (66%) were affected by at least one shortage daily.
- 40

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41 The survey results revealed concerning trends:

- Approximately 90% of respondents experienced rationing, restricting, and hoarding of drug supplies.
- Many commented on waste (for example, 250ml bags of insulin but only a small fraction is needed).
- Survey participants noted other strategies that are being employed including re-deploying medications used for crash carts, reusing vials, extending hang times for IVs, purchasing sterile products compounded from non-sterile ingredients from compounding pharmacies without evaluating the risk, and transitioning infusion devices to push IVs (changing nurse
- 50 protocols).

- 15% admitted to purchasing drugs in short supply at great cost from a secondary gray market.
- Most survey participants (71%) were unable, at times, to provide patients with the recommended drug or treatment for their condition due to shortages, which resulted in patients receiving a less effective drug and delayed treatments. Many participants also stated that they need full-time staff to manage drug shortages and commented that the tasks associated with this process reduce the time available for direct patient care. Additionally, many respondents provided examples of how recent drug shortages have led to unsafe practices that have increased the risk of, or contributed to, a medication error.
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12	SUMMARY
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Although recent natural disasters have increased the number of drug shortages only slightly, shortages of basic products such as saline and SVPs, and their containers, are significantly impacting the health care system by affecting patient care, increasing the potential for drug errors, and influencing the manner in which health care teams function. Box 1 is a compilation of resources available to assist physicians and hospitals in mitigating drug shortages.

18 19

20 Information and discussion at an ASHP-convened roundtable on current issues regarding drug

21 shortages illuminated additional relevant policy considerations such as manufacturer transparency

22 regarding production location and the cause(s) of shortages, quality of outsourcer compounding

23 facilities, and the potential inclusion of vital drug manufacturing sites as critical infrastructure.

24

Given its role as the leading advocacy organization for physicians and a key advocate for patients, patient care, and the public health, our AMA is concerned about the shortages of basic medical supplies such as sterile saline, medications for which the vehicle for intravenous administration is

sterile saline, and any containers for sterile saline or injectable medications which are a component

- 29 of our nation's drug shortage problems. The AMA welcomes the application of critical
- 30 infrastructure terminology and policies to the drug shortage challenges clinicians face each day.
- 31

## 32 RECOMMENDATION

33

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

36

37 National Drug Shortages

 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 <u>are in short</u> supply experience drug shortages, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.

Our AMA supports authorizing the Secretary of <u>the U.S. Department of</u> 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.

47 3. Our AMA will advocate that the US Food and Drug Administration (FDA) and/or Congress
48 require drug manufacturers to establish a plan for continuity of supply of vital and life-

49 sustaining medications and vaccines to avoid production shortages whenever possible. This

50 plan should include establishing the necessary resiliency and redundancy in manufacturing

1		capability to minimize disruptions of supplies in foreseeable circumstances including the
2		possibility of a disaster affecting a plant.
3	4.	The Council on Science and Public Health shall continue to evaluate the drug shortage issue
4		and report back at least annually to the House of Delegates on progress made in addressing
5		drug shortages.
6	5.	Our AMA urges the development of a comprehensive independent report on the root causes of
7		drug shortages. Such an analysis should consider federal actions, the number of manufacturers,
8		economic factors including federal reimbursement practices, as well as contracting practices by
9		market participants on competition, access to drugs, and pricing. In particular, further
10		transparent analysis of economic drivers is warranted. The federal Centers for Medicare &
11		Medicaid Services (CMS) should review and evaluate its 2003 Medicare reimbursement
12		formula of average sales price plus 6% for unintended consequences including serving as a root
13		cause of drug shortages.
14	6.	Our AMA urges regulatory relief designed to improve the availability of prescription drugs by
15		ensuring that such products are not removed from the market due to compliance issues unless
16	_	such removal is clearly required for significant and obvious safety reasons.
17	7.	Our AMA supports the view that wholesalers should routinely institute an allocation system
18		that attempts to fairly distribute drugs in short supply based on remaining inventory and
19	0	considering the customer's purchase history.
20	8.	Our AMA will collaborate with medical specialty <u>society</u> partners <u>and other stakeholders</u> in
21		identifying and supporting legislative remedies to allow for more reasonable and sustainable
22	~	payment rates for prescription drugs.
23	9.	Our AMA urges that during the evaluation of potential mergers and acquisitions involving
24		pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to
25	10	determine whether such an activity has the potential to worsen drug shortages.
26	10.	Our AMA urges the FDA to require manufacturers to provide greater transparency regarding
27		production locations of drugs and provide more detailed information regarding the causes and
28		anticipated duration of drug shortages.
29	11.	Our AMA encourages electronic health records (EHR) vendors to make changes to their
30	10	systems to ease the burden of making drug product changes.
31	12.	Our AMA urges the FDA to evaluate and provide current information regarding the quality of
32	10	outsourcer compounding facilities.
33	13.	Our AMA urges DHHS and the U.S. Department of Homeland Security (DHS) to examine and
34 25		consider drug shortages as a national security initiative and include vital drug production sites
33 26	14	<u>In the critical initiastructure plan.</u>
30 27	14.	Our ANA considers drug snortages to be an urgent public nearin crisis, and recent shortages
31 20		nave had a dramatic and negative impact on the delivery and safety of appropriate health care
38		to patients. (Modify Current HOD Policy)

Fiscal Note: Less than \$500

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#### Box 1. Resources available to assist in mitigation of drug shortages.

- 1. ASHP Resource Center
- 2. ASHP <u>list</u> of current shortages
- 3. ASHP and University of Utah <u>guidance</u> on small-volume parenteral solutions shortages
- 4. ASHP and University of Utah <u>guidance</u> on injectable opioid shortages
- 5. <u>FDA Drug Shortages Page</u> (includes current shortages list, mobile app, and additional information)
- 6. <u>US Department of Health and Human Services' Office of the Assistant Secretary for</u> <u>Preparedness and Responsehttp://www.ismp.org/sc?id=3072</u>
- 7. <u>ISMP newsletter</u> on managing drug shortages
- 8. American Society for Parenteral and Enteral Nutrition <u>guidance</u> on shortages with parenteral nutrition components
- 9. <u>NEJM article</u> detailing Brigham and Women's Hospital Oral Rehydration Protocol<sup>17</sup>

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

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

#### APPENDIX



Note: Each column represents the number of new shortages identified during that year. University of Utah Drug Information Service <u>Erin.Fox@hsc.utah.edu</u>, @foxerinr

Figure 2.



Note: Each column represents the number of active shortages at the end of each quarter. University of Utah Drug Information Service <u>Erin.Fox@hsc.utah.edu</u>, @foxerinr Figure 3.

## Active Shortages Top 5 Drug Classes



Figure 4.





University of Utah Drug Information Service <u>Erin.Fox@hsc.utah.edu</u>, @foxerinr

CSAPH Report 3-A-18

	Subject:	Prescription Drug Donation (Resolution 207-I-17 and Resolution 525-A-17)
	Presented by:	Robert Gilchick, MD, MPH, Chair
	Referred to:	Reference Committee E (Douglas Martin, MD, Chair)
1 2 3	Resolution 207 and Reuse Pro Delegates aske	7-I-17, "Redistribution of Unused Prescription Drugs to Pharmaceutical Donation grams," introduced by the Medical Student Section and referred by the House of ed:
4 5 6 7 8 9	That our A promote m the state le AMA Poli	American Medical Association work with appropriate stakeholders to draft and nodel legislation aimed at developing better funding for drug donation programs on evel provided these programs follow the quality assurance guidelines set by existing cy H-280.959.
9 10 11 12	Resolution 525 Medical Staff	5-A-17, "Providing for Prescription Drug Donation," introduced by the Organized Section and referred by the House of Delegates asked:
12 13 14 15 16 17	That our A 1) nursing offices and need who recycle can	American Medical Association advocate for new federal legislation that would allow: homes to recycle prescription drugs that are unused, sealed, and dated; 2) physician d clinics to donate prescription drugs that are unused, sealed, and dated to patients in are uninsured or underinsured; and, 3) cancer programs and clinics to accept and ncer-specific drugs to patients in need who are uninsured or underinsured.
19 20 21	Both of these r expiration of u patient access	resolutions reflect concerns about the intersection of rising drug costs, wastage and nused pharmaceutical products prompting their disposal, and existing problems with and their ability to pay for needed therapies.
22 23 24 25 26 27	The Council pr and their clinic to prescription establish or rea	reviously examined the issue of pharmaceutical expiration (and beyond use) dates cal and fiscal consequences. <sup>1</sup> Expiration and beyond use dates are tangentially related drug donation and/or recycling because they are fundamental criteria used to affirm the integrity of returned products.
27 28 29 30 31 32 33 34 35	A fundamental prescription m prescription m lessen prescrip quantities of p drug treatment evaluated. The unused medica	I goal expressed by both resolutions is minimizing the quantity of unused edications while decreasing healthcare costs. A prevailing issue is how unused edications that have been dispensed can be safely returned and reused. One way to tion drug waste on the front end is for physicians and other prescribers to limit rescription medications for acute therapy and/or during the initiation (trial phase) of for a chronic condition when the safety and efficacy of such treatment is being e other approach, which is the focus of this report, is to recycle and re-dispense ations

1	CURRENT	AMA	POLICY
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The AMA has well developed policy on the recycling of nursing home drugs based on a Council 3 report issued in 1997.<sup>2</sup> At the time, it was estimated that nearly 7% of monthly medication costs 4 5 were going to waste in this setting due to patient death, discontinuation of medication, a change in 6 medication, patient transfer or hospitalization. Policy H-280.959, "Recycling of Nursing Home 7 Drugs," supports the return and reuse of medications to the dispensing pharmacy to reduce waste 8 associated with unused medications in long-term care facilities (LTCFs) provided the following 9 conditions are satisfied: 10 11 The returned medications are not controlled substances. • 12 • The medications are dispensed in tamper-evident packaging and returned with packaging intact 13 (e.g., unit dose, unused injectable vials and ampules). 14 In the professional judgment of the pharmacist, the medications meet all federal and state • 15 standards for product integrity. Policies and procedures are followed for the appropriate storage and handling of medications at 16 • the LTCF and for the transfer, receipt, and security of medications returned to the dispensing 17 18 pharmacy. 19 A system is in place to track re-stocking and reuse to allow medications to be recalled if • 20 required. 21 22 CURRENT STATUS OF PRESCRIPTION DRUG DONATION/REUSE PROGRAMS 23 24 Complicating the issue of recycling or medication reuse is guidance from the U.S. Food and Drug 25 Administration (FDA) (CPG Sec. 460.300, "Return of Unused Prescription Drugs to Pharmacy Stock") that states: 26 27 28 "A pharmacist should not return drugs products to his stock once they have been out of his 29 possession. It could be a dangerous practice for pharmacists to accept and return to stock the 30 unused portions of prescriptions that are returned by patrons, because he would no longer have 31 any assurance of the strength, quality, purity or identity of the articles." 32 33 Furthermore, 34 35 "The pharmacist or doctor dispensing a drug is legally responsible for all hazards of 36 contamination or adulteration that may arise, should he mix returned portions of drugs to his 37 shelf stocks. Some of our investigations in the past have shown that drugs returned by patrons 38 and subsequently resold by the pharmacist were responsible for injuries." 39 40 The language from the compliance guide is advisory in nature. 41 42 While Resolution 525-A-17 seeks federal legislation to support the recycling of "nursing home 43 drugs," both medical and pharmacy practice are regulated by the states. Our AMA supports state 44 regulated medical and pharmacy practice. Increasingly state legislation, federal legislation, and regulations affecting activities of the FDA (e.g., risk evaluation and mitigation strategies) and 45 46 certain policies implemented by payers, pharmaceutical benefit management companies, and 47 pharmacy chains are restricting prescriber behavior, especially with respect to the use of opioid 48 analgesics and other controlled substances. With respect to the specific issues raised in this report, 49 states regulate such activities, therefore the federal approach advocated for in Resolution 525-A-17

50 is not further evaluated or recommended.

#### CSAPH Rep. 3-A-18 -- page 3 of 6

1 National Association of Boards of Pharmacy Position Statement and Model Legislation 2 3 Resolution 207-I-17 seeks to draft and promote model legislation aimed at developing better 4 funding for drug donation programs on the state level, as long as such programs follow the quality 5 assurance guidelines described in Policy H-280,959. In October 2012, the National Association of Boards of Pharmacy (NABP) convened a task force on "Drug Return and Reuse Programs" to 6 7 develop a position statement and revise its model act that addresses "the circumstances in both the 8 community setting and in state-mandated-repository programs under which previously dispensed 9 medications may be re-dispensed to patients."<sup>3</sup> 10 Return and Reuse of Prescription Drugs. NABP "endorses the return and reuse of medications that 11 have been maintained in a closed system." A closed system is defined as the "delivery to and/or 12 13 return of prescription medication from a healthcare or other institutional facility, which is 14 maintained in a controlled environment under a health care practitioner and not the patient." This 15 approach helps ensure the integrity of the medication. Prescription drugs should only be returned and reused when the drugs were removed from the pharmacy for delivery by pharmacy staff, a 16 17 pharmacy contracted delivery service, or approved common carrier and the drugs were returned 18 immediately, either because they were "not deliverable" or the patient refused to accept the 19 delivery. Additionally, the returned product must remain packaged in the manufacturer's original, 20 sealed, and tamper-evident packaging, or the dispensing pharmacy's original packaging. If an 21 approved common carrier is used, product quality also must meet United States Pharmacopeia 22 (USP) standards. Additional criteria that must be met for return and reuse include: 24 All returned packaging must indicate that product integrity and stability has been maintained. • 25 All returned packaging must have been returned on the same day as the attempted delivery and • must be evaluated to ensure it is not adulterated or could be considered misbranded. 26 27 • A state-licensed pharmacist must verify compliance with all of the above elements. 29 Prescription Drug Repository Programs. In contrast to the limited and unique circumstances described for a "return and reuse" program, a prescription drug repository program would be able to accept drugs that are not confined to a delivery service. Although NABP "does not endorse the reuse of medications that have left closed distribution systems," for states that establish repositories, such programs should be registered and under the jurisdiction of the Board of 33 Pharmacy and be subject to inspection. Strict criteria would apply to the policies, procedures and qualification of acceptable medications for reuse. Controlled substances are not accepted, and the 35 36 medication must be judged to be unadulterated, unexpired, and in unopened unit dose or manufacturer's tamper-resistant original packaging. Additionally, such drugs must have been originally dispensed by a pharmacist or practitioner acting within their scope of practice, and upon return be kept in a separate inventory and undergo monthly expiration date review with record keeping. 41 42 In recent years, several states have legalized and implemented charitable return and reuse programs 43 involving drugs obtained from various donation sources. According to the 2018 Survey of 44 Pharmacy Law, 42 states currently have authorized prescription drug repository programs.<sup>4</sup> A few states that have not authorized repository programs allow return and reuse; with few exceptions, 45 46 states that have authorized repositories also allow return and reuse. In some cases repositories are 47 operational only for long term care facilities and/or correctional institutions, or charitable 48 recipients, or the program only accepts products directly from wholesalers, distributors, or 49 hospitals; in some cases medications are accepted from outpatients. In general, the provisions in 50 enacted legislation are comparable to the requirements contained in the NABP model legislation. 51 Differences may exist regarding which non-controlled drugs are accepted, criteria for eligible

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1 donors and recipients, protocols for transfer and repackaging, whether the program is centralized or

de-centralized, and how it is funded. A 2016 summary of state prescription drug return, reuse, and

3 recycling laws compiled by the National Conference of State Legislatures (NCSL) concluded that

nearly half of the enacted laws were not operational. Some "common obstacles are the lack of
 awareness about the programs, no central agency or entity designated to operate and fund the

awareness about the programs, no central agency or entity designated to operate and fund the program, and added responsibilities for repository sites that accept donations."<sup>5</sup> A summary of

relevant state laws with links to their operational sites is maintained by NCSL.<sup>5</sup>

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

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in free medications and supplies over the last decade.<sup>6</sup> Recipients at or below 200% of the federal poverty level as well as individuals who are uninsured or under-insured are eligible to receive donated drugs in their original sealed container or in tamper-evident packaging.

Established in 2007, the Iowa program has served 70,000 patients and redistributed \$15 million

- receive donated drugs in their original sealed container or in tamper-evident packaging.
  Since beginning in 2007, the Wyoming program has helped residents fill more than 150,000 prescriptions (worth more than \$12.5 million).<sup>7,8</sup> In 2016, the program provided more than \$2.4 million worth of donated prescription medications free of charge on a short term basis.
- Oklahoma law allows the transfer of drugs from nursing homes to the Tulsa County Pharmacy.
   Since the start of the program in 2004 through January 2018, more than 223,000 prescriptions at a savings of \$22 million have been dispensed.<sup>9</sup>
- In California, Supporting Initiatives to Redistribute Unused Medicine (SIRUM) was 21 • 22 established. SIRUM is an online community matching drug donations with low-income safetynet health clinics whose patients could benefit from the medications.<sup>10</sup> Unexpired drugs are 23 collected from manufacturers, wholesalers, pharmacies and health facilities. Medicines go to 24 25 clinics and pharmacies and are dispensed to low-income patients; more than 150,000 patients 26 have been helped. SIRUM also operates the Colorado program which focuses on oncologic 27 products. A few other states also either focus on cancer/immunosuppressant drugs or allow 28 them in their repositories.
- 29

## 30 DISCUSSION

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32 A substantial majority of states have authorized drug repository and/or return and reuse programs 33 for prescription medications that are unexpired and in their original container or tamper proof 34 packaging. Repository programs must address concerns with allowing donation and reuse of 35 medications that have left controlled environments such as a pharmacy or institutional facility. 36 Such concerns may include storage conditions affecting product integrity and issues specific to 37 accepting drugs back into the supply chain that have left licensed entities that are part of the normal 38 supply chain with track and trace requirements (i.e., possible counterfeiting or other substandard 39 drug sources). Nearly half of the authorized programs in existence do not appear to be operational. 40 Model state legislation to establish "return and reuse" or drug repository programs is available 41 from the NABP. Such programs have the potential to provide pharmaceutical care to patients who 42 cannot afford their medications, reduce waste and environmental disposal, and reduce healthcare 43 costs. Several states have demonstrated measurable success in implementing these types of 44 programs.

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

- 5 6 Our AMA encourages:
- States with laws establishing prescription drug repository and/or "return and reuse" programs
   to implement such laws and to consider integrating them with existing recycling or disposal
   programs. (New AMA Policy)
- 10
- States that lack drug repository and/or "return and reuse" programs to enact such laws in consultation with their state board of pharmacy. (New AMA Policy).
- 13
- State medical associations in states where there is a prescription drug repository or a "return and reuse" program for unused medication supplies to educate physicians in their state regarding the existence of such programs. (New AMA Policy).

Fiscal Note: less than \$500

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Resolution: 501 (A-18)

	Introduced by:	American Society of Addiction Medicine
	Subject:	Synthetic Cannabinoids
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)
1 2 3	Whereas, Synthe recently been gai	etic cannabinoid receptor agonists, such as JWH-018 and HU-210, have ining popularity as psychoactive substances <sup>1</sup> ; and
4 5 6 7	Whereas, These potent than delta and	synthetic substances are full agonists at cannabinoid receptors, are more -9-tetrahydrocannabinol (THC), and can cause severe illness and even death <sup>2</sup> ;
8 9 10 11	Whereas, Synthe abrupt cessation these substances	tic cannabinoid use can lead to physical and psychological dependence, with of use after long-term use leading to withdrawal-like symptoms, suggesting are addictive <sup>3</sup> ; and
12 13 14 15	Whereas, Some the United States THC; therefore b	persons elect to use them since they can be obtained legally in many parts of and are not detected by most standard drug screens, including assays for e it
16 17 18 19 20	RESOLVED, Tha such as JWH-018 "K2", are potent a smoked or consu	It our American Medical Association recognize that synthetic cannabinoids 3, JWH-210, and other compounds sold by "street" names such as "Spice" and agonists in the mammalian endocannabinoid system and are dangerous when imed (New HOD Policy); and be it further
20 21 22 23 24 25	RESOLVED, That the federal Contro- with no currently be it further	It our AMA advocate that the Schedule I status of synthetic cannabinoids under olled Substances Act should be retained since these compounds are "drugs accepted medical use and a high potential for abuse" (New HOD Policy); and
26 27 28 29	RESOLVED, Tha considering chan that synthetic car use, sale and dis	It our AMA advocate that in any state or other jurisdiction in the U.S. ges in the legal status of cannabis, those changes should make explicitly clear mabinoids are unsafe and unfit for human consumption and their possession, tribution by persons of all ages should remain illegal. (New HOD Policy)

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

Received: 04/17/18

 <sup>&</sup>lt;sup>1</sup> Trecki J, Gerona RR, Schwartz MD. Synthetic Cannabinoid – Related Illnesses and Deaths. N Engl J Med. 2015;373(2):103-107.
 <sup>2</sup> Tait RJ, Caldicott D, Mountain D, Hill SL, Lenton S. A systematic review of adverse events arising from the use of synthetic cannabinoids and their associated treatment. Clin Toxicol (Phila). 2016;54(1):1-13.
 <sup>3</sup> Centers for Disease Control and Prevention (CDC). (2017) "Synthetic Cannabinoids: An Overview for Healthcare Providers." Available at: <a href="https://www.cdc.gov/nceh/hsb/chemicals/sc/healthcare.html#one">https://www.cdc.gov/nceh/hsb/chemicals/sc/healthcare.html#one</a>

#### **RELEVANT AMA POLICY**

#### Cannabis Legalization for Recreational Use H-95.924

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

CSAPH Rep. 05, I-17

Resolution: 502 (A-18)

	Introduced by:	Colorado, Mississippi, Oregon
	Subject:	Expedited Prescription CBD Drug Rescheduling
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)
1 2 3	Whereas, Almost thirty percent of th convulsant medic	500,000 children in the United States suffer from epilepsy and approximately nose children's seizures are not adequately controlled by current anti- ations; and
4 5 6 7	Whereas, Childho Gastaut syndrome seizures resistant	ood-onset, encephalopathic epilepsies, such as Dravet syndrome and Lennox e, are even more treatment resistant, with as many as 80-90% of children's to available anti-convulsant medications; and
0 9 10 11	Whereas, There is treatment options	s an urgent need for new U.S. Food and Drug Administration (FDA)-approved for these childhood encephalopathies; and
12 13	Whereas, Cannat (tetrahydrocannat	bidiol has no effect on the receptors that produce euphoria with THC binol); and
15 16 17	Whereas, Recent promising treatme	controlled clinical trials with cannabidiol (CBD) suggest that CBD may be a ent option for these encephalopathies; and
18 19 20	Whereas, In the a to these unapprovand	bsence of an FDA-approved CBD medication, desperate families are turning ved cannabis and CBD products in an effort to reduce their child's seizures;
22 23 24 25	Whereas, Many medical claims of and in 2015, 2016 manufacturers, re	nanufacturers of unapproved CBD products sold online make unsupported safety and efficacy, including that their products will treat epilepsy and cancer, 6, and 2017, the FDA sent Warning Letters to a number of these quiring them to cease making such claims; and
20 27 28 29 30 31	Whereas, CBD is states' laws and, t rescheduling, eac prescribers to sell	classified in Schedule I or is defined as marijuana under virtually all of the therefore, upon FDA approval and U.S. Drug Enforcement Administration h state must make changes to state law in order for pharmacies and and dispense CBD containing medication; and
32 33 34 35	Whereas, The new FDA approved, to encephalopathies	ed to make such changes to state law to allow a CBD medication, once it is be dispensed may result in a delay in access for children suffering from such ; and
36 37 38 39	Whereas, If state obtaining FDA-ap may require distril that are not consis	laws are not corrected to allow medical dispensing, the only option for proved medication may require registration on special state patient registries, bution through cannabis dispensaries, and may impose labeling requirements stent with FDA-approved labeling; therefore be it

- 1 RESOLVED, That our American Medical Association encourage state controlled substance
- 2 authorities, boards of pharmacy, and legislative bodies to take the necessary steps including
- 3 regulation and legislation to reschedule U.S. Food and Drug Administration (FDA)-approved
- 4 cannabidiol products, or make any other necessary regulatory or legislative change, as
- 5 expeditiously as possible so that they will be available to patients immediately after approval by
- 6 the FDA and rescheduling by the U.S. Drug Enforcement Administration (New HOD Policy); and
- 7 be it further
- 8
- 9 RESOLVED, That our AMA advocate that an FDA-approved cannabidiol medication should be
- 10 governed only by the federal and state regulatory provisions that apply to other prescription-only
- 11 products, such as dispensing through pharmacies, rather than by these various state laws
- 12 applicable to unapproved cannabis products. (New HOD Policy)

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

Received: 04/25/18

Resolution: 503 (A-18)

Introduced by:	Medical Student Section
Subject:	Advocating for Anonymous Reporting of Overdoses by First Responders and Emergency Physicians
Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)

1 Whereas, The rate of overdose deaths involving opioids in the United States increased two hundred percent between 2000 and 2014:<sup>1</sup> and 2

3

4 Whereas, Nineteen states experienced a statistically significant increase in opioid related 5 deaths between 2014 and 2015;<sup>1</sup> and

6

7 Whereas, There is a scarcity of data regarding non-fatal overdoses that would be beneficial 8 when implementing real-time, community-specific opioid overdose prevention programs;<sup>2</sup> and

9

10 Whereas, One shared purpose for the introduction of overdose reporting policies in several 11 states was to allow for real time monitoring of areas most at-risk, resulting in immediate 12 response through preventative measures (such as Naloxone distribution) to those areas with rises in overdose rates;<sup>3,4,5,6,7</sup> and 13 14

15 Whereas, Overdose monitoring enables a state's Department of Health to better understand risk factors for death among those with similar exposures or evaluate the potential benefits of 16

programs put in place to respond to the epidemic;<sup>5</sup> and 17

18

19 Whereas, It is imperative that health departments and other relevant stakeholders are provided with accurate, timely, and actionable information on drug-related overdose;<sup>8</sup> therefore be it 20

21

22 RESOLVED. That our American Medical Association support non-fatal and fatal opioid 23 overdose reporting to the appropriate agencies. (New HOD Policy)

<sup>5</sup>*Rules and Regulations Pertaining to Opioid Overdose Reporting - R23-10I0IDR*. NOPERI.org; 2014.

<sup>6</sup>Texas Legislature. *Mandatory Reporting of Overdoses - SB* 43. Texas Legislature; 1999.

http://poisoncontrol.org/providers/mandatory-overdose-reporting/. Accessed September 5, 2017.

<sup>7</sup>Blau M, McCrea R. As new and lethal opioids flood U.S. streets, crime labs race to ID them. STAT News.

<sup>&</sup>lt;sup>1</sup> Rudd RA, Aleshire N, Zibbell JE, Gladden MR. Increases in Drug and Opioid Overdose Deaths -- United States, 2000-2014. Morb Mortal Wkly Rep. 2016;64(50 & 51):1378-1382. https://www.cdc.gov/mmwr/pdf/wk/mm6450.pdf. Accessed September 5, 2017. <sup>2</sup>Madah-Amiri D, Clausen T, Myrmel L, Brattebø G, Lobmaier P. Circumstances surrounding non-fatal opioid overdoses attended by ambulance services. Drug Alcohol Rev. 2017;36(3):288-294. doi:10.1111/dar.12451. <sup>3</sup>Gancarski AG. Mandatory overdose reporting bill filed in Florida House. Florida Politics. http://floridapolitics.com/archives/230429-

mandatory-overdose-reporting-bill-filed-florida-house. Published 2017. Accessed September 5, 2017.

<sup>&</sup>lt;sup>4</sup>Office of the Arizona Governor. Governor Ducey Issues Executive Order To Increase Reporting Of Opioid-Related Data. Office of the Governor - Doug Ducey. https://azgovernor.gov/governor/news/2017/06/governor-ducey-issues-executive-order-increasereporting-opioid-related-data. Accessed September 5, 2017.

http://www.noperi.org/files/misc/HEALTH emergency regs reporting.pdf. Accessed September 5, 2017.

https://www.statnews.com/2017/07/05/opioid-identification-analogs/. Published 2017. Accessed September 5, 2017.

<sup>&</sup>lt;sup>8</sup>The Network for Public Health Law. Overdose Reporting Requirements: Fact Sheet.; 2017. https://www.networkforphl.org/\_asset/nrlzcb/overdose-reporting-requirements.pdf. Accessed September 20, 2017.

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

Date Received: 04/26/18

**RELEVANT AMA POLICY** 

#### Increasing Availability of Naloxone H-95.932

1. Our AMA supports legislative, regulatory, and national advocacy efforts to increase access to affordable naloxone, including but not limited to collaborative practice agreements with pharmacists and standing orders for pharmacies and, where permitted by law, community based organization, law enforcement agencies, correctional settings, schools, and other locations that do not restrict the route of administration for naloxone delivery.

2. Our AMA supports efforts that enable law enforcement agencies to carry and administer naloxone.

3. Our AMA encourages physicians to co-prescribe naloxone to patients at risk of overdose and, where permitted by law, to the friends and family members of such patients.

4. Our AMA encourages private and public payers to include all forms of naloxone on their preferred drug lists and formularies with minimal or no cost sharing.

5. Our AMA supports liability protections for physicians and other health care professionals and others who are authorized to prescribe, dispense and/or administer naloxone pursuant to state law.

6. Our AMA supports efforts to encourage individuals who are authorized to administer naloxone to receive appropriate education to enable them to do so effectively.

7. Our AMA encourages manufacturers or other qualified sponsors to pursue the application process for over the counter approval of naloxone with the Food and Drug Administration.

8. Our AMA urges the Food and Drug Administration to study the practicality and utility of Naloxone rescue stations (public availability of Naloxone through wall-mounted display/storage units that also include instructions).

BOT Rep. 22, A-16 Modified: Res. 231, A-17 Modified: Speakers Rep. 01, A-17 Appended: Res. 909, I-17

#### 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.

Citation: Res. 526, A-06; Modified in lieu of Res. 503, A-12; Appended: Res. 909, I-12; Reaffirmed: BOT Rep. 22, A-16;

Resolution: 504 (A-18)

Introduced by:	Medical Student Section
Subject:	Ending the Risk Evaluation and Mitigation Strategy (REMS) policy on Mifepristone (Mifeprex)
Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)

Whereas, The Food and Drug Administration (FDA) often regulates medications by associating
 them with a drug-specific Risk Evaluation and Mitigation Strategy (REMS), with the goal of
 ensuring a drug's benefits outweigh its potential risks;<sup>1</sup> and

Whereas, The FDA REMS policy states that "Mifeprex<sup>®</sup> must be dispensed to patients only in
certain healthcare settings, specifically clinics, medical offices, and hospitals" and prevents the
distribution of mifepristone (Mifeprex<sup>®</sup>) through retail pharmacies;<sup>2</sup> and

8

9 Whereas, A woman is 14 times more likely to die from pregnancy-related complications than
 10 taking mifepristone for a medical abortion;<sup>3</sup> and

11

17

Whereas, The estimated mortality rate of Mifeprex<sup>©</sup> is 0.00063% based on data from 3 million
women in the United States who have used the medication for abortion;<sup>3</sup> and

Whereas, The FDA's REMS for Mifeprex<sup>©</sup> impedes the provision of Mifeprex<sup>©</sup>, even after over a
 decade of safe use, without offering any demonstrated or even reasonably likely advantage;<sup>1,4</sup> and

Whereas, American College of Obstetricians and Gynecologists and the *New England Journal of Medicine*, among other prominent organizations, have called for the removal of the Mifeprex
 REMS given the drug's history of safe use;<sup>1,4</sup> therefore be it

RESOLVED. That our American Medical Association support efforts urging the Food and Drug

Administration to lift the Risk Evaluation and Mitigation Strategy on mifepristone. (New HOD

24 Policy)

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

Received: 04/26/18

<sup>4</sup> ACOG Statement on Medication Abortion. ACOG Statement on Medication Abortion - ACOG.https://www.acog.org/About-ACOG/News-Room/Statements/2016/ACOG-Statement-on-Medication-Abortion. March 30, 2016.

<sup>&</sup>lt;sup>1</sup>FDA Basics: A Brief Overview of Risk Evaluation and Mitigation Strategies (REMS). US FDA. July 27, 2017.

<sup>&</sup>lt;sup>2</sup>Mifeprex REMS. US Food and Drug Administration. 2016. https://www.accessdata.fda.gov/drugsatfda\_docs/rems/Mifeprex\_2016-03-29\_REMS\_document.pdf

<sup>&</sup>lt;sup>3</sup>Mifeprex REMS Study Group. Sixteen Years of Overregulation: Time to Unburden Mifeprex. *New England Journal of Medicine*. 2017;376(8):790-794.

#### **RELEVANT AMA POLICY**

## The Evolving Culture of Drug Safety in the United States: Risk Evaluation and Mitigation Strategies (REMS) H-100.961

Our AMA urges that:

(1) The Food and Drug Administration (FDA) issue a final industry guidance on Risk Evaluation and Mitigation Strategies (REMS) with provisions that: (a) require sponsors to consult with impacted physician groups and other key stakeholders early in the process when developing REMS with elements to assure safe use (ETASU); (b) establish a process to allow for physician feedback regarding emerging issues with REMS requirements; (c) clearly specify that sponsors must assess the impact of ETASU on patient access and clinical practice, particularly in underserved areas or for patients with serious and life threatening conditions, and to make such assessments publicly available; and (d) conduct a long-term assessment of the prescribing patterns of drugs with REMS requirements.

(2) The FDA ensure appropriate Advisory Committee review of proposed REMS with ETASU before they are finalized as part of the premarket review of New Drug Applications, and that the Drug Safety and Risk Management Advisory Committee fulfills this obligation for drugs that are already on the market and subject to REMS because of new safety information.

(3) To the extent practicable, a process is established whereby the FDA and sponsors work toward standardizing procedures for certification and enrollment in REMS programs, and the common definitions and procedures for centralizing and standardizing REMS that rely on ETASU are developed.

(4) REMS-related documents intended for patients (e.g., Medication Guides, acknowledgment/consent forms) be tested for comprehension and be provided at the appropriate patient literacy level in a culturally competent manner.

(5) The Food and Drug Administration (FDA) issue a final industry guidance on Risk Evaluation and Mitigation Strategies (REMS) with provisions that: (a) urge sponsors to consult with impacted physician groups and other key stakeholders early in the process when developing REMS with elements to assure safe use (ETASU); (b) establish a process to allow for physician feedback regarding emerging issues with REMS requirements; and (c) recommend that sponsors assess the impact of ETASU on patient access and clinical practice, particularly in underserved areas or for patients with serious and life threatening conditions, and to make such assessments publicly available.

(6) The FDA, in concert with the pharmaceutical industry, evaluate the evidence for the overall effectiveness of REMS with ETASU in promoting the safe use of medications and appropriate prescribing behavior.

(7) The FDA ensure appropriate Advisory Committee review of proposed REMS with ETASU before they are finalized as part of the premarket review of New Drug Applications, and that the Drug Safety and Risk Management Advisory Committee fulfills this obligation for drugs that are already on the market and subject to REMS because of new safety information.

(8) To the extent practicable, a process is established whereby the FDA and sponsors work toward standardizing procedures for certification and enrollment in REMS programs, and the common definitions and procedures for centralizing and standardizing REMS that rely on ETASU are developed.

(9) REMS-related documents intended for patients (e.g., Medication Guides, acknowledgment/consent forms) be tested for comprehension and be provided at the appropriate patient literacy level in a culturally competent manner.

(10) The FDA solicit input from the physician community before establishing any REMS programs that require prescriber training in order to ensure that such training is necessary and meaningful, requirements are streamlined and administrative burdens are reduced.

Citation: (CSAPH Rep. 8, A-10; Reaffirmed: Res. 917, I-10; Appended: CSAPH Rep. 3, I-12)

See also:

Physician Awareness and Education About Pharmaceutical and Biological RiskEvaluation and Mitigation D-100.971Pregnancy Termination H-5.983Policy on Abortion H-5.990Abortion H-5.995Medical Training and Termination of Pregnancy H-295.923Freedom of Communication Between Physicians and Patients H-5.989

Resolution: 505 (A-18)

	Introduced by:	Medical Student Section
	Subject:	Researching Drug Facilitated Sexual Assault Testing
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)
1 2 3	Whereas, It is est suspected to be c	imated that 10–12 % of sexual assault victims in emergency rooms are Irug facilitated sexual assault (commonly known as date rape) victims; <sup>1</sup> and
5 4 5 6 7	Whereas, In a nat drugs without thei assaulted while u	tional college survey, 5.3% of undergraduate women report having been given r knowledge or consent and 0.6% of all surveyed women have been sexually nder the influence of a drug given without their knowledge or consent; <sup>2</sup> and
7 8 9	Whereas, Of the 3 only three had a b	31 women in this national survey who reported drug-facilitated sexual assault, blood or urine sample taken to test for drugs; <sup>2</sup> and
10 11 12 13	Whereas, Establis date rape drugs; <sup>3</sup>	shed accurate methods exist for testing the biological presence of common <sup>4,5</sup> and
14 15 16 17	Whereas, Federa giving a victim a c therefore be it	I law provides penalties up to 20 years of imprisonment when rape involves Irug without the victim's knowledge, rendering a charge very serious; <sup>1</sup>
18 19 20 21	RESOLVED, Tha offering drug testi gamma-hydroxyb (Directive to Take	t our American Medical Association study the feasibility and implications of ng at point of care for date rape drugs, including rohypnol, ketamine, and utyrate, in cases of suspected non-consensual, drug-facilitated sexual assault. Action)
		hat hat waar \$1,000 \$5,000

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

Received: 04/26/18

<sup>&</sup>lt;sup>1</sup> Ashok, J., Nair, M., & Friedman, R. (2016). Drug-Facilitated Sexual Assaults. In Sexual Offending (pp. 67-77). Springer New York. <sup>2</sup> Krebs, C. P., Lindquist, C. H., Warner, T. D., Fisher, B. S., & Martin, S. L. (2007). The campus sexual assault (CSA) study: Final report. Washington, DC: National Institute of Justice, US Department of Justice. <sup>3</sup> Negrusz, A. & Gaensslen, R.E. (2013). Drug-facilitated sexual assault. In Negrusz, A. & Cooper, G.A.A (Eds.), Clarke's analytical

forensics and toxicology. London, United Kingdom: Pharmaceutical Press

<sup>&</sup>lt;sup>4</sup> Birkler, R. I. D., Telving, R., Ingemann-Hansen, O., Charles, A. V., Johannsen, M., & Andreasen, M. F. (2012). Screening analysis for medicinal drugs and drugs of abuse in whole blood using ultra-performance liquid chromatography time-of-flight mass spectrometry (UPLC-TOF-MS)-Toxicological findings in cases of alleged sexual assault. Forensic science international, 222(1), 154-161.

<sup>&</sup>lt;sup>5</sup>Xiang, P., Shen, M., & Drummer, O. H. (2015). Drug concentrations in hair and their relevance in drug facilitated crimes. Journal of forensic and legal medicine, 36, 126-135.

## **RELEVANT AMA POLICY:**

## Sexual Assault Survivor Services H-80.998

Our AMA supports the function and efficacy of sexual assault survivor services, supports state adoption of the sexual assault survivor rights established in the Survivors' Bill of Rights Act of 2016, encourages sexual assault crisis centers to continue working with local police to help sexual assault survivors, and encourages physicians to support the option of having a counselor present while the sexual assault survivor is receiving medical care.

Citation: Res. 56, A-83; Reaffirmed: CLRPD Rep. 1, I-93; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15; Modified: Res. 202, I-17;

#### Sexual Assault Survivors H-80.999

1. Our AMA supports the preparation and dissemination of information and best practices intended to maintain and improve the skills needed by all practicing physicians involved in providing care to sexual assault survivors.

2. Our AMA advocates for the legal protection of sexual assault survivors rights and work with state medical societies to ensure that each state implements these rights, which include but are not limited to, the right to: (A) receive a medical forensic examination free of charge, which includes but is not limited to HIV/STD testing and treatment, pregnancy testing, treatment of injuries, and collection of forensic evidence; (B) preservation of a sexual assault evidence collection kit for at least the maximum applicable statute of limitation; (C) notification of any intended disposal of a sexual assault evidence kit with the opportunity to be granted further preservation; (D) be informed of these rights and the policies governing the sexual assault evidence kit; and (E) access to emergency contraception information and treatment for pregnancy prevention.

3. Our AMA will collaborate with relevant stakeholders to develop recommendations for implementing best practices in the treatment of sexual assault survivors, including through engagement with the joint working group established for this purpose under the Survivor's Bill of Rights Act of 2016.

Citation: Sub. Res. 101, A-80; Reaffirmed: CLRPD Rep. B, I-90; Reaffirmed: Sunset Report, I-00; Reaffirmed: CSAPH Rep. 1, A-10; Modified: Res. 202, I-17;

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

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

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

## Addressing Sexual Assault on College Campuses H-515.956

Our AMA supports universities' implementation of evidence-driven sexual assault prevention programs that specifically address the needs of college students and the unique challenges of the collegiate setting.

Citation: Res. 402, A-16;

Resolution: 506 (A-18)

	Introduced by:	Medical Student Section
	Subject:	Non-Therapeutic Gene Therapies
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)
1 2 3	Whereas, Gene th prevent disease";	nerapy is defined as "an experimental technique that uses genes to treat or and
4 5 6 7	Whereas, Gene the effective in pro insulin-like growth	nerapies in both human clinical trials and murine models have been shown to moting endogenous production of various proteins such as erythropoietin, factor-1, and vascular endothelial growth factor; <sup>2,3,4,5,6</sup> and
8 9 10	Whereas, While the considering the po	ne therapeutic benefits of such technology is promising, many are also otential for misuse of such technology, including "gene doping"; and
11 12 13	Whereas, In 2008 "nontherapeutic u the capacity to en	, the World Anti-Doping Agency (WADA) defined gene doping as the se of cells, genes, genetic elements, or modulation of gene expression, having hance performance."; <sup>7,8</sup> and
15 16 17 18 19 20	Whereas, Althoug potential societal a prophylactic inves many of the major Committee (IOC),	h to date there have been no confirmed instances of gene doping, the and health related consequences of gene doping have prompted a tigation into detection techniques and the denouncement of such activity by governing bodies in this arena, including the International Olympic WADA, and various International Sports Federations; <sup>9,10,11</sup> and
21 22	Whereas, While the use of gene dopin	ne major institutional bodies relevant to doping in sports have condemned the g, public opinion may diverge, as recent evidence suggests that the general

https://ghr.nlm.nih.gov/primer/therapy/genetherapy. Accessed September 6, 2017.

<sup>5</sup>Human Stem Cell Institute, Russia. Efficiency, Safety and Portability of Neovasculgen (Neovasculgen). Available from: <u>https://clinicaltrials.gov/ct2/show/NCT03068585</u>. NLM identifier: NCT03068585. Accessed September 20, 2017.

<sup>&</sup>lt;sup>1</sup> What is gene therapy? - Genetics Home Reference. U.S. National Library of Medicine.

<sup>&</sup>lt;sup>2</sup>Blum, S. et al. TARGT Gene Therapy Platform for Correction of Anemia in End-Stage Renal Disease. New England Journal of Medicine. 2017 Jan.;376(2):189-191.

<sup>&</sup>lt;sup>3</sup>Hösel, M. et al. Autophagy determines efficiency of liver-directed gene therapy with adeno-associated viral vectors. Hepatology. 2017 Jul.;66(1):252-265.

<sup>&</sup>lt;sup>4</sup>Deev, R. et al. Results of an International Postmarketing Surveillance Study of pl-VEGF165 Safety and Efficacy in 210 Patients with Peripheral Arterial Disease. American Journal of Cardiovascular Drugs. 2017 Jan.;17(3):235-242.

<sup>&</sup>lt;sup>6</sup>Eibel, B. et al. VEGF gene therapy cooperatively recruits molecules from the immune system and stimulates cell homing and angiogenesis in refractory angina. Cytokine. 2017 Mar.;91:44-50.

<sup>&</sup>lt;sup>7</sup>Brzeziańska, E. *et al.* Gene Doping In Sport – Perspectives And Risks. *Biology of Sport.* 2014 Sep.;31(4):251-259. <sup>8</sup>Momaya, A. *et al.* Performance-Enhancing Substances in Sports: A Review of the Literature. *Sports Medicine.* 2015 Apr.;45(4):517-531

<sup>&</sup>lt;sup>9</sup>Unal, M and Unal, DO. Gene Doping in Sports. Sports Medicine. 2004;34(6):357-362.

<sup>&</sup>lt;sup>10</sup>Murray TH. A Moral Foundation for Anti-Doping: How Far Have We Progressed? Where Are the Limits? Acute Topics in Anti-Doping Medicine and Sport Science. 2017 Jun;62:186-193.

<sup>&</sup>lt;sup>11</sup>Murray TH. A Moral Foundation for Anti-Doping: How Far Have We Progressed? Where Are the Limits? Acute Topics in Anti-Doping Medicine and Sport Science. 2017 Jun;62:186-193.

- 1 population may be in greater support of gene doping without consideration for ethical and medical repercussions:<sup>12,13</sup> and 2
- 3
- 4 Whereas, Though the major sequelae of gene doping are still uncertain, potential long term 5 effects have manifested as cancers, heart failure, and stroke:<sup>8,14</sup> and
- 6

7 Whereas, While there is speculation that the technology to adequately detect gene doping in athletes already exists, no standardized protocol has yet to be developed for the detection or 8 regulation of any type of gene doping in athletes:14,15,16,17 and 9

10

11 Whereas, While our AMA has recognized and supported the potential therapeutic effects of 12 genomic editing (AMA Policy H-480.945) and denounced the use of pharmacologic substances for non-therapeutic purposes (H-470.994, H-470.972, H-470.978), it has not vet established a 13 14 position regarding the various non-therapeutic applications and genetic manipulation of such

- 15 technology; therefore be it
- 16

17 RESOLVED, That our American Medical Association partner with relevant institutions to

encourage the development of safety guidelines, regulations, and permissible uses of 18

19 performance enhancing, non-therapeutic gene therapies. (Directive to Take Action)

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

Received: 04/26/18

## **RELEVANT AMA POLICY:**

#### Non-Therapeutic Use of Pharmacological Agents by Athletes H-470.994

Our AMA: (1) opposes the use of drugs for the purpose of enhancing athletic performance or sustaining athletic achievement. This action in no way should be construed as limiting a physician's proper use of drugs in indicated treatment of athletic injuries or clinical symptoms of individual athletes; and (2) endorses efforts by state level high school athletic associations to establish programs which include enforceable guidelines concerning weight and body fat changes on a precompetition basis for those sports in which weight management is a concern. Citation: (Res. 89 part 2, A-72; Reaffirmed: CLRPD Rep. C, A-89; Modified by Res. 401, I-95; Reaffirmed: CSA Rep. 8, A-05; Reaffirmed: CSAPH Rep. 1, A-15)

#### Medical and Nonmedical Uses of Anabolic-Androgenic Steroids H-470.972

Our AMA (1) reaffirms its concern over the nonmedical use of drugs among athletes, its belief that drug use to enhance or sustain athletic performance is inappropriate, its commitment to cooperate with various other concerned organizations, and its support of appropriate education and rehabilitation programs; (2) actively encourages further research on short- and long-term health effects, and encourages reporting of suspected adverse effects to the FDA; and (3) supports continued efforts to work with sports organizations to increase understanding of health effects and to discourage use of steroids on this basis.

Citation: (CSA Rep. A, I-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: Res. 501, A-01; Modified: CSA Rep. 9, A-03; Modified: CSAPH Rep. 1, A-13)

See also: Blood Doping H-470.978; Genome Editing and its Potential Clinical Use H-480.945

<sup>&</sup>lt;sup>12</sup>Polcz, S and Lewis, A. Welcoming Prometheus: Experimental Support for Deregulating Gene Doping. SSRN Electronic Journal. 2017 May.

<sup>&</sup>lt;sup>13</sup>Polcz, Ś and Lewis, A. Welcoming Prometheus: Experimental Support for Deregulating Gene Doping. SSRN Electronic Journal. 2017 May.

<sup>&</sup>lt;sup>4</sup>Salamin, O. et al. Erythropoietin as a performance-enhancing drug: Its mechanistic basis, detection, and potential adverse effects. Molecular and Cellular Endocrinology. 2017 Jan.;S0303-7207(17):30045-X

<sup>&</sup>lt;sup>15</sup>Robinson, N. et al. The Athlete Biological Passport: How to Personalize Anti-Doping Testing across an Athlete's Career? Acute

Topics in Anti-Doping Medicine and Sport Science. 2017 Jun.;62:107-118. <sup>16</sup>Zhang, JJ. et al. Detection of exogenous gene doping of IGF-I by a real-time quantitative PCR assay. Biotechnology and Applied Biochemistry. 2017 Jul.;64(4):549-554.

<sup>&</sup>lt;sup>17</sup>Bowers LD and Bigard X. Achievements and Challenges in Anti-Doping Research. Acute Topics in Anti-Doping Medicine and Sport Science. 2017 Jun.;62:77-90.

Resolution: 507
(A-18)

123456789011231456718902122345	Introduced by:	Medical Student Section			
	Subject:	Opioid Treatment Programs Reporting to Prescription Monitoring Programs			
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)			
	Whereas, Complete knowledge of a patient's opioid medication history is necessary for physicians to provide the best care, allows for open, honest dialogue and shared decision making; <sup>1</sup> and				
	Whereas, Prescription monitoring programs can provide information to physicians that may not be available within their electronic health records system about patients' current and past opioid use, tolerance, potential drug interactions, and other risk factors the patient may have; and				
	Whereas, Usage of prescription monitoring programs may prevent dangerous prescribing patterns and limit polypharmacy; <sup>2</sup> and				
	Whereas, Incomp monitoring progra	lete or inaccurate information limits providers' ability to utilize prescription ms; <sup>3</sup> and			
	Whereas, Opioid to state prescription	treatment programs do not currently report prescribing and dispensing activity on monitoring programs; <sup>4</sup> and			
	Whereas, Patients prescribed interfe	s on opioid replacement therapy are at high risk for overdose and being ring medications such as benzodiazepines or other opioids; <sup>5</sup> and			
	Whereas, Opioid obtained from opi opioid or benzodia cases that the pat	treatment information in the prescription monitoring programs, which is oid treatment programs, will help prevent other physicians from prescribing azepine medications that could interfere with medication assisted treatment in tient does not disclose their treatment; therefore be it			
25 26 27 28	RESOLVED, Tha Treatment and Pr	t our American Medical Association amend Policy D-95.980, "Opioid escription Drug Monitoring Programs," by deletion as follows:			
29 30	Our AMA will s programs to re	eek changes to <del>allow states the flexibility to</del> require opioid treatment port to prescription monitoring programs. (Modify Current HOD Policy)			

<sup>&</sup>lt;sup>1</sup> Ali, M. M., Dowd, W. N., Classen, T., Mutter, R., & Novak, S. P. (2017). Prescription drug monitoring programs, nonmedical use of prescription drugs, and heroin use: Evidence from the National Survey of Drug Use and Health. Addictive Behaviors, 69, 65-77. doi:10.1016/j.addbeh.2017.01.011

<sup>&</sup>lt;sup>2</sup>Baehren D, Marco C, Droz D, Sinha S, Callan E, Akpunonu P. A statewide prescription monitoring program affects emergency department prescribing behaviors. Ann Energ Med. 2010; 1:19-23.

<sup>&</sup>lt;sup>3</sup>Carnes N, Wright E, and Norwood C. A qualitative analysis of prescribers' and dispensers' views on improving prescription drug monitoring programs. Res Social Adm Pharm. 2016. pii: S1551-7411(16)30230-3. doi: 10.1016/j.sapharm.2016.12.002. <sup>4</sup>Clark W. Letter on Opioid Treatment Programs and Prescription Drug Monitoring Programs. SAMHSA. 2011.

<sup>&</sup>lt;sup>5</sup>Methadone maintenance treatment. Clinical guidelines for withdrawal management and treatment of drug dependence in closed settings. WHO Guidelines. Geneva. 2009.

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

Date Received: 04/26/18

#### **RELEVANT AMA POLICY:**

#### **Opioid Treatment and Prescription Drug Monitoring Programs D-95.980**

Our AMA will seek changes to allow states the flexibility to require opioid treatment programs to report to prescription monitoring programs. Citation: (BOT Rep. 11, A-10)

Citation: (BOT Rep. 11, A-10)

#### Drug Abuse Related to Prescribing Practices H-95.990

1. Our AMA recommends the following series of actions for implementation by state medical societies concerning drug abuse related to prescribing practices:

A. Institution of comprehensive statewide programs to curtail prescription drug abuse and to promote appropriate prescribing practices, a program that reflects drug abuse problems currently within the state, and takes into account the fact that practices, laws and regulations differ from state to state. The program should incorporate these elements: (1) Determination of the nature and extent of the prescription drug abuse problem; (2) Cooperative relationships with law enforcement, regulatory agencies, pharmacists and other professional groups to identify "script doctors" and bring them to justice, and to prevent forgeries, thefts and other unlawful activities related to prescription drugs; (3) Cooperative relationships with such bodies to provide education to "duped doctors" and "dated doctors" so their prescribing practices can be improved in the future; (4) Educational materials on appropriate prescribing of controlled substances for all physicians and for medical students. B. Placement of the prescription drug abuse programs within the context of other drug abuse control efforts by law enforcement, regulating agencies and the health professions, in recognition of the fact that even optimal prescribing practices will not eliminate the availability of drugs for abuse purposes, nor appreciably affect the root causes of drug abuse. State medical societies should, in this regard, emphasize in particular: (1) Education of patients and the public on the appropriate medical uses of controlled drugs, and the deleterious effects of the abuse of these substances; (2) Instruction and consultation to practicing physicians on the treatment of drug abuse and drug dependence in its various forms.

2. Our AMA: A. promotes physician training and competence on the proper use of controlled substances; B. encourages physicians to use screening tools (such as NIDAMED) for drug use in their patients; C. will provide references and resources for physicians so they identify and promote treatment for unhealthy behaviors before they become life-threatening; and D. encourages physicians to query a state's controlled substances databases for information on their patients on controlled substances.

3. The Council on Science and Public Health will report at the 2012 Annual Meeting on the effectiveness of current drug policies, ways to prevent fraudulent prescriptions, and additional reporting requirements for state-based prescription drug monitoring programs for veterinarians, hospitals, opioid treatment programs, and Department of Veterans Affairs facilities.

4. Our AMA opposes any federal legislation that would require physicians to check a prescription drug monitoring program (PDMP) prior to prescribing controlled substances.

Citation: (CSA Rep. C, A-81; Reaffirmed: CLRPD Rep. F, I-91; Reaffirmed: Sunset Report, I-01; Reaffirmed: CSAPH Rep. 1, A-11; Appended: Res. 907, I-11; Appended: Res. 219, A-12; Reaffirmation A-15; Reaffirmed: BOT Rep. 12, A-15; Reaffirmed: BOT Rep. 5, I-15)

See also: <u>Prescription Drug Monitoring Program Confidentiality H-95.946</u>; <u>Prescription Drug Monitoring to Prevent Abuse of Controlled Substances H-95.947</u>; <u>Universal Prescriber Access to Prescription Drug Monitoring Programs H-95.927</u>; <u>Support for Prescription Drug Monitoring Programs H-95.929</u>

Resolution: 508
(A-18)

	Introduced by:	Medical Student Section			
$\begin{array}{c}1&2&3&4\\5&6&7&8\\9&10&11&2\\13&14&5&6\\17&18&19&22&2\\22&24&25&26\\27&28\end{array}$	Subject:	Reintroduction of Mitochondrial Donation in the United States			
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)			
	Whereas, Mitochc	ondrial diseases are estimated to affect approximately 1 in 4300 adults; <sup>1</sup> and			
	Whereas, There a at symptom allevia	are no existing cures for mitochondrial diseases and current therapy is aimed ation and haltering disease progression; <sup>2</sup> and			
	Whereas, The in vitro technique known as mitochondrial donation was introduced in 1995 as a means of decreasing the incidence of inherited mitochondrial diseases; <sup>2,3</sup> and				
	Whereas, Mitochondrial donation is a technique that involves the replacement of a prospective mother's oocyte cytoplasm, containing defective mitochondria, with healthy donor oocyte cytoplasm; <sup>4</sup> and				
	Whereas, As of 20 estimated that over	002, the FDA's Biological Response Modifiers Advisory Committee (BRMAC) er two dozen births had occurred in the US using this technique; <sup>5</sup> and			
	Whereas, While data on the wellbeing and long-term health of these individuals is not available, research on monkeys conceived via mitochondrial donation suggests that the technique produces viable, healthy offspring; <sup>6</sup> and				
	Whereas, BRMAC recommends that "any future work in mitochondrial donation procedures must be cleared by the FDA under Investigational New Drug exemptions" on the grounds that these births represented the first cases of human germline genetic modification; <sup>5</sup> and				
	Whereas, In 2016 question only repr and it rejected a w limited to male em to subsequent ger	, the Institute of Medicine released a statement that claimed the techniques in resent a modification of the germline when used to produce female offspring, wholesale prohibition of this research, and advised that the technique be hbryos for the time being, such that the modifications would not be carried on herations; <sup>7</sup> and			

<sup>&</sup>lt;sup>1</sup> G.S. Gorman, A.M. Schaefer, Y. Ng, et al., Prevalence of nuclear and mitochondrial DNA mutations related to adult mitochondrial disease, Ann. Neurol. 77 (5) (2015) 753–759.

 <sup>&</sup>lt;sup>2</sup> Craven, L., Murphy, J., Turnbull, D. M., Taylor, R. W., Gorman, G. S., & McFarland, R. (2018). Scientific and Ethical Issues in Mitochondrial Donation. *The New Bioethics*, *24*(1), 57–73. http://doi.org.proxy.lib.mcw.edu/10.1080/20502877.2018.1440725
 <sup>3</sup> Rubenstein, Donald S., David C. Thomasma, Eric A. Schon, and Michael J. Zinaman. "Germ-Line Therapy to Cure Mitochondrial Disease: Protocol and Ethics of In Vitro Ovum Nuclear Transplantation." *Cambridge Quarterly of Healthcare Ethics* 4.03 (1995): 316.
 <sup>4</sup> Wolf, Don P., et al. "Mitochondrial Replacement Therapy in Reproductive Medicine." *Trends in Molecular Medicine*, vol. 21, no. 2, 2015. pp. 68–76., doi:10.1016/i.molmed.2014.12.001.

 <sup>&</sup>lt;sup>5</sup> "BRMAC Briefing Document for Day 1, May 9, 2002." Biological Response Modifiers Advisory Committee. US Food and Drug Administration. 2002.
 <sup>6</sup> "Mitochondrial replacement techniques: Ethical, social, and policy considerations." *National Academies of Sciences, Engineering,*

<sup>&</sup>lt;sup>6</sup> "Mitochondrial replacement techniques: Ethical, social, and policy considerations." *National Academies of Sciences, Engineering, and Medicine.* National Academy Press. 2016.

<sup>&</sup>lt;sup>7</sup> Tachibana M, Amato P, Sparman M, et al. Towards germline gene therapy of inherited mitochondrial diseases. *Nature*. 2013;493(7434):627-631. doi:10.1038/nature11647.

- 1 Whereas, In 2015, the UK's Human Fertilisation and Embryology Authority determined that the
- 2 benefits outweigh the risks associated with mitochondrial donation, and the technique was
- 3 subsequently legalized, making it available to the thousands of couples who could potentially
- 4 benefit from it; <sup>8</sup> and
- 5
- 6 Whereas, The FDA is prohibited from accepting applications for clinical research using
- 7 mitochondrial replacement therapy as stipulated under federal law; <sup>9</sup> therefore be it
- 8
- 9 RESOLVED, That our American Medical Association support regulated research to determine
- 10 the efficacy and safety of mitochondrial donation as a means of preventing the transmission of
- 11 mitochondrial diseases. (New HOD Policy)

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

Received: 04/26/18

#### **RELEVANT AMA POLICY:**

#### E-7.3.6 Research in Gene Therapy & Genetic Engineering

Gene therapy involves the replacement or modification of a genetic variant to restore or enhance cellular function or the improve response to nongenetic therapies. Genetic engineering involves the use of recombinant DNA techniques to introduce new characteristics or traits. In medicine, the goal of gene therapy and genetic engineering is to alleviate human suffering and disease. As with all therapies, this goal should be pursued only within the ethical traditions of the profession, which gives primacy to the welfare of the patient.

In general, genetic manipulation should be reserved for therapeutic purposes. Efforts to enhance desirablecharacteristics or to improve complex human traits are contrary to the ethical tradition of medicine. Because of the potential for abuse, genetic manipulation of nondisease traits or the eugenic development of offspring may never be justifiable.

Moreover, genetic manipulation can carry risks to both the individuals into whom modified genetic material is introduced and to future generations. Somatic cell gene therapy targets nongerm cells and thus does not carry risk to future generations. Germ-line therapy, in which a genetic modification is introduced into the genome of human gametes or their precursors, is intended to result in the expression of the modified gene in the recipient's offspring and subsequent generations. Germ-line therapy thus may be associated with increased risk and the possibility of unpredictable and irreversible results that adversely affect the welfare of subsequent generations.

Thus in addition to fundamental ethical requirements for the appropriate conduct of research with human participants, research in gene therapy or genetic engineering must put in place additional safeguards to vigorously protect the safety and well-being of participants and future generations.

Physicians should not engage in research involving gene therapy or genetic engineering with human participants unless the following conditions are met:

(a) Experience with animal studies is sufficient to assure that the experimental intervention will be safe and effective and its results predictable.

(b) No other suitable, effective therapies are available.

(c) Gene therapy is restricted to somatic cell interventions, in light of the far-reaching implications of germ-line interventions.

(d) Evaluation of the effectiveness of the intervention includes determination of the natural history of the disease or condition under study and follow-up examination of the participants' descendants.

(e) The research minimizes risks to participants, including those from any viral vectors used.

(f) Special attention is paid to the informed consent process to ensure that the prospective participant (or legally authorized representative) is fully informed about the distinctive risks of the research, including use of viral vectors to deliver the modified genetic material, possible implications for the participants descendants, and the need for follow-up assessments.

Physicians should be aware that gene therapy or genetic engineering interventions may require additional scientific and ethical review, and regulatory oversight, before they are introduced into clinical practice. AMA Principles of Medical Ethics: I,V,VII

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law.

İssued: 2016

<sup>&</sup>lt;sup>8</sup> Craven, Lyndsey, Mary Herbert, Alison Murdoch, Julie Murphy, James Lawford Davies, and Doug M. Turnbull. "Research into Policy: A Brief History of Mitochondrial Donation." Stem Cells 34.2 (2015): 265-67.

<sup>&</sup>lt;sup>9</sup> Cellular & Gene Therapy Products - Advisory on Legal Restrictions on the Use Of Mitochondrial Replacement Techniques To Introduce Donor Mitochondria Into Reproductive Cells Intended For Transfer Into a Human Recipient Center for Biologics Evaluation and Research - https://www.fda.gov/BiologicsBloodVaccines/CellularGeneTherapyProducts/ucm570185.htm

Resolution: 509 (A-18)

	Introduced by:	Medical Student Section		
	Subject:	Opposing the Classification of Cannabidiol as a Schedule 1 Drug		
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)		
1 2 3	Whereas, Tetrahydrocannabinol (THC) is the primary psychoactive substance found in marijuana products, while Cannabidiol (CBD) is a chemically distinct compound found in marijuana products with no known psychoactive effects; <sup>1</sup> and			
5 6 7 8	Whereas, CBD is not addictive and has been shown to produce anxiolytic, antipsychotic, antidepressant, and neuroproductive effects; <sup>2,3,4</sup> and and			
9 10 11	Whereas, In one s 36.5% reduction i	study, patients ages 1-30 years old with treatment resistant epilepsy had a in monthly motor seizures over a 12-week treatment period with CBD; <sup>3,4</sup> and		
12 13 14 15 16 17	Whereas, CBD is of multiple scleros in Canada for bot neural circuits link treatment for subs	effective in pain management with minimal side effects, particularly in cases sis and intractable cancer pain, and has been approved as a pain medication h conditions, <sup>45</sup> as well as having documented positive impacts on many sed to addiction and drug-seeking behaviors, making it a potentially effective stance abuse disorders without significant side effects; <sup>5,6</sup> and		
18 19 20	Whereas, In 2016 Pharmaceuticals Complex; <sup>6,7</sup> and	the U.S. Food and Drug Administration granted Orphan Drug status to GW for Epidiolex $^{ m I\!R}$ (cannabidiol) for the treatment of Tuberous Sclerosis		

<sup>&</sup>lt;sup>1</sup> Borgelt LM, Franson KL, Nussbaum AM, Wang GS. The pharmacologic and clinical effects of medical cannabis.

Pharmacotherapy: The Journal of Human Pharmacology and Drug Therapy. 2013;33(2):195-209. doi:10.1002/phar.1187. <sup>2</sup> Campos AC, Moreira FA, Gomes FV, Bel EAD, Guimaraes FS. Multiple mechanisms involved in the large-spectrum therapeutic potential of cannabidiol in psychiatric disorders. *Philosophical Transactions of the Royal Society B: Biological Sciences*. 2012;367(1607):3364-3378. doi:10.1098/rstb.2011.0389.

<sup>&</sup>lt;sup>3</sup> Jutras-Aswad D, Prud'Homme M, Cata R. Cannabidiol as an Intervention for Addictive Behaviors: A Systematic Review of the Evidence. *Substance Abuse: Research and Treatment.* 2015:33. doi:10.4137/sart.s25081.

<sup>&</sup>lt;sup>4</sup> Devinsky O, Marsh E, Friedman D, et al. Cannabidiol in patients with treatment-resistant epilepsy: an open-label interventional trial. *The Lancet Neurology*. 2016;15(3):270-278. doi:10.1016/s1474-4422(15)00379-8.

 <sup>&</sup>lt;sup>5</sup> Russo E. Cannabinoids in the management of difficult to treat pain. *Therapeutics and Clinical Risk Management*. 2008; Volume 4:245-259. doi:10.2147/tcrm.s1928..
 <sup>6</sup>Musty RE. Possible Anxiolytic Effects Of Cannabidiol. *The Cannabinoids: Chemical, Pharmacologic, and Therapeutic Aspects*.

 <sup>&</sup>lt;sup>6</sup>Musty RE. Possible Anxiolytic Effects Of Cannabidiol. *The Cannabinoids: Chemical, Pharmacologic, and Therapeutic Aspects*. 1984:795-813. doi:10.1016/b978-0-12-044620-9.50057-9.
 <sup>7</sup> GW Pharmaceuticals Receives Orphan Drug Designation from FDA for Cannabidiol for the Treatment of Tuberous Sclerosis

<sup>&</sup>lt;sup>7</sup> GW Pharmaceuticals Receives Orphan Drug Designation from FDA for Cannabidiol for the Treatment of Tuberous Sclerosis Complex. *GW Pharmaceuticals*. April 2016. https://www.gwpharm.com/about-us/news/gw-pharmaceuticals-receives-orphan-drugdesignation-fda-cannabidiol-treatment-tuberous. Accessed September 6, 2017.

1 Whereas, The DEA has established a new drug code for marijuana extracts that moves all 2 extracts "containing one or more cannabinoids that has been derived from any plant of the 3 genus Cannabis, other than the separated resin (whether crude or purified) obtained from the plant" to a Schedule 1 drug (including CBD) DEA Schedule I drugs are defined as those with no 4 5 accepted medical benefits, a high potential for abuse, or those that are not considered safe for human consumption, and Schedule 1 substances cannot be prescribed and can only be 6 administered under federally approved research programs; <sup>8,9,10</sup> and 7 8 9 Whereas, Moving CBD to a Schedule 1 drug removes its availability to patients benefiting from 10 these effects in states without medical marijuana and significantly slows medical research in CBD trials:<sup>11</sup> and 11 12 13 Whereas, The Justice Department has installed new research proposals for medical marijuana and 14 has asked Congress to block statutory medical marijuana protections with new appropriations language, while pursuing criminal prosecution for individuals using marijuana:<sup>12</sup> and 15 16 Whereas, The non-psychoactive<sup>2</sup>, non-addictive<sup>3</sup> properties of CBD address the stated 17 concerns of the Justice Department regarding psychoactive drug use and abuse potential;<sup>12</sup> 18 19 therefore be it 20 21 RESOLVED, That our American Medical Association support the reclassification of Cannabidiol 22 as a non-scheduled drug. (New HOD Policy)

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

Received: 04/26/18

## **RELEVANT AMA POLICY:**

#### 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; and (5) believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions. CSAPH Rep. 05, I-17

See also: Cannabis and Cannabinoid Research H-95.952

<sup>&</sup>lt;sup>8</sup> Establishment of a New Drug Code for Marihuana Extract. Vol 81.; 2016.

<sup>&</sup>lt;sup>9</sup> Drug Schedules. DEA / Drug Scheduling. https://www.dea.gov/druginfo/ds.shtml. Accessed September 20, 2017.

 <sup>&</sup>lt;sup>10</sup> Mead A. The legal status of cannabis (marijuana) and cannabidiol (CBD) under U.S. law. *Epilepsy & Behavior*. 2017;70:288-291. doi:10.1016/j.yebeh.2016.11.021.
 <sup>11</sup> Ingraham C. Jeff Sessions personally asked Congress to let him prosecute medical-marijuana providers. *Wall Street Journal*.

<sup>&</sup>lt;sup>11</sup> Ingraham C. Jeff Sessions personally asked Congress to let him prosecute medical-marijuana providers. *Wall Street Journal*. https://www.washingtonpost.com/news/wonk/wp/2017/06/13/jeff-sessions-personally-asked-congress-to-let-him-prosecute-medicalmarijuana-providers/?utm\_term=.6b70fbbc9986. Published June 13, 2017. Accessed September 20, 2017.

<sup>&</sup>lt;sup>12</sup> Sessions JB. Department of Justice Appropriations. May 2017.

American Society of Clinical Oncology

	Subject:	Alcohol Use and Cancer
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)
1 3 4 5 6 7 8 9 10 11 12 3	Whereas, Alcoh cancer, including	ol use is a recognized modifiable risk factor for several common types of g liver, esophageal, oropharyngeal, laryngeal, breast and colon <sup>1</sup> ; and
	Whereas, Betwe that 88,000 deat	en 2006 and 2010, the Centers for Disease Control and Prevention reported hs <sup>2</sup> were attributed to excessive alcohol use in the United States; and
	Whereas, Althou even light alcoho pharyngeal, and	igh the greatest risk of cancer is associated with high levels of consumption of consumption is associated with a higher risk of esophageal, oral cavity and breast cancers with relative risks of 1.26, 1.13, and 1.04 respectively <sup>3</sup> ; and
	Whereas, The W a 5% increase ir cancer per 10 gr	/orld Cancer Research Fund/American Institute for Cancer Research estimates premenopausal breast cancer and a 9% increase in postmenopausal breast rams of ethanol consumed per day <sup>4</sup> ; and
14 15 16 17	Whereas, Drinki an underappreci	ng of alcohol, without the development of alcoholism or alcohol dependence, is ated cause of cancer; and
17 18 19 20	Whereas, Many poses to health,	people engage in excessive drinking without recognition of the risk factors it including increased risk of developing cancer; and
20 21 22 23	Whereas, The Ir carcinogen⁵; the	nternational Agency for Research on Cancer classified alcohol as a group 1 refore be it
24 25 26	RESOLVED, Th factor for cancer	at our American Medical Association recognize alcohol use as a modifiable risk (New HOD Policy); and be it further
27 28 29	RESOLVED, Th between alcohol	at our AMA support research and educational efforts about the connection use and several types of cancer (New HOD Policy); and be it further
30 31	RESOLVED, Th use and cancer.	at our AMA encourage physicians to counsel patients on the risks of alcohol (New HOD Policy)

Introduced by:

<sup>&</sup>lt;sup>1</sup> LoConte, Noelle et al. Alcohol and Cancer: A Statement of the American Society of Clinical Oncology. J Clin Onc 2018 36:1, 83-

<sup>93.</sup> <sup>2</sup> Centers for Disease Control and Prevention: Alcohol use and health. <u>http://www.cdc.gov/alcohol/fact-sheets/alcohol-use.htm</u> <sup>3</sup> Bagnardi V, Rota M, Botteri E, et al: Alcohol consumption and site-specific cancer risk: A comprehensive dose-response meta-

analysis. Br J Cancer 112:580-593, 2015. <sup>4</sup> World Cancer Research Fund: Diet, nutrition, physical activity and breast cancer. <u>http://www.wcrf.org/sites/default/files/CUP\_BREAST\_REPORT\_2017\_WEB.pdf</u> <sup>5</sup> World Cancer Research Fund/American Institute for Cancer Research: Food, Nutrition, Physical Activity, and the Prevention of Cancer: A Global Perspective. Washington, DC, American Institute for Cancer Research, 2007.

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

Received: 05/02/18

#### **RELEVANT AMA POLICY**

#### Alcohol Abuse and the War on Drugs H-30.972

Our AMA (1) supports documenting the strong correlation between alcohol abuse and other substance abuse; (2) reaffirms the concept that alcohol is an addictive drug and its abuse is one of the nation's leading drug problems; and (3) encourages state medical societies to work actively with drug task forces and study committees in their respective states to assure that their scope of study includes recognition of the strong correlation between alcohol abuse and other substance abuse and recommendations to decrease the immense number of health, safety, and social problems associated with alcohol abuse. Citation: (Sub. Res. 97, I-89; Reaffirmed: Sunset Report, A-00; Reaffirmed: CSAPH Rep. 1, A-10)

#### Alcohol Use Disorder and Unhealthy Alcohol Use Among Women H-30.943

The AMA recognizes the prevalence of unhealthy use of alcohol among women, as well as current barriers to diagnosis and treatment. The AMA urges physicians to be alert to the presence of alcohol-related problems among women and to screen all patients for alcohol us disorder and dependence. The AMA encourages physicians to educate women of all ages about their increased risk of damage to the nervous system, liver and heart disease from alcohol and about the effect of alcohol on the developing fetus. The AMA encourages adequate funding for research to explore the nature and extent of alcohol use disorder and unhealthy alcohol use, and variations in alcohol use among ethnic and other subpopulations. The AMA encourages all medical education programs to provide greater coverage on alcohol as a significant source of morbidity and mortality in women.

Citation: CSA Rep. 5, I-97; Reaffirmed: CSAPH Rep. 3, A-07; Modified: CSAPH Rep. 01, A-17;

#### Screening and Brief Interventions For Alcohol Problems H-30.942

Our AMA in conjunction with medical schools and appropriate specialty societies advocates curricula, actions and policies that will result in the following steps to assure the health of patients who use alcohol: (a) Primary care physicians should establish routine alcohol screening procedures (e.g., CAGE) for all patients, including children and adolescents as appropriate, and medical and surgical subspecialists should be encouraged to screen patients where undetected alcohol use could affect care. (b) Primary care physicians should learn how to conduct brief intervention counseling and motivational interviewing. Such training should be incorporated into medical school curricula and be subject to academic evaluation. Physicians are also encouraged to receive additional education on the pharmacological treatment of alcohol use disorders and co-morbid problems such as depression, anxiety, and post-traumatic stress disorder. (c) Primary care clinics should establish close working relationships with alcohol treatment specialists, counselors, and self-help groups in their communities, and, whenever feasible, specialized alcohol and drug treatment programs should be integrated into the routine clinical practice of medicine.

Citation: (CSA Rep. 14, I-99; Reaffirmation I-01; Modified: CSAPH Rep. 1, A-11)

		Resolution: 511			
	Introduced by:	Oklahoma (A-18)			
1 2 2	Subject:	Education for Recovering Patients On Opiate Use After Sobriety			
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)			
	Whereas, Accord Americans die af	ding to the National Institute on Drug Abuse, every day more than 115 ter overdosing on opioids and these are our patients; and			
3 4 5 6 7	Whereas, Drug of and continue to r last 3 years, mor withdrawal the m	overdoses in the State of Oklahoma have increased by 91% in the last 15 years ise. We lose nearly 1,000 Oklahomans per year due to a drug overdose. In the e than 1,300 newborns tested positive for substance exposure and went into ioment they were born; and			
8 9 10 11 12 13 14	Whereas, Anecdotally, a common death scenario is when recovering opioid abuse patient takes their usual dose of opioids after a prolonged period of sobriety; and				
	Whereas, AMA F at-risk patients, i patients after sig	Policy D-95.987, "Prevention of Opioid Overdose," is to educate physicians and t does not specifically address education needs of recovering opioid abuse nificant sobriety time; therefore be it			
15 16	RESOLVED, Tha	at our AMA amend Policy D-95-987 by addition to read as follows:			
17	Prevention of	Opioid Overdose D-95.987			
19 20 21 22 23 24 25 26 27 28	1. Our AMA: ( abuse places compassionat offering naloxe implemented i the education preventing op initiatives and	A) recognizes the great burden that opioid addiction and prescription drug on patients and society alike and reaffirms its support for the e treatment of such patients; (B) urges that community-based programs one and other opioid overdose prevention services continue to be n order to further develop best practices in this area; and (C) encourages of health care workers and opioid users about the use of naloxone in ioid overdose fatalities; and (D) will continue to monitor the progress of such respond as appropriate.			
29 30 31 32 33	2. Our AMA w caregivers in t continued stud methods for p	ill: (A) advocate for the appropriate education of at-risk patients and their he signs and symptoms of opioid overdose; and (B) encourage the dy and implementation of appropriate treatments and risk mitigation atients at risk for opioid overdose.			
34 35 36	3. That our AN abuse patients result in overc	A implement an appropriate education program for recovering opioid a and their friends/families that opioid use after significant sobriety time can lose and death. (Modify Current HOD Policy)			

Fiscal Note: Minimal - less than \$1,000. Received: 05/01/18
## **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.

Citation: Res. 526, A-06; Modified in lieu of Res. 503, A-12; Appended: Res. 909, I-12; Reaffirmed: BOT Rep. 22, A-16

Resolution: 512 (A-18)

	Introduced by:	Illinois	
12345678901123145671890212234567890112314567189021223456789011233456789011233456789031323333333333333333333333333333333333	Subject:	Physician and Patient Education About the Risk of Synthetic Cannabinoid Use	
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)	
	Whereas, Cannal possession and u	Whereas, Cannabis is a psychoactive drug with a well-defined addiction potential, and its possession and use are now legal in many states under various circumstances; and	
	Whereas, The active compound in cannabis is THC (tetrahydrocannabinol), which is a ligand that binds to CB1 and CB2 receptors in the central nervous system and elsewhere; and		
	Whereas, Completely synthetic ligands for the CB1 receptor have been identified and synthesized, and are used to produce euphoria and related psychoactive effects, and go by street names such as "Spice" and "K2"; and		
	Whereas, The drugs known as synthetic cannabinoids have no medical indications, but are used by inhalation or ingestion primarily for their psychoactive effects; and		
	Whereas, These drugs are not manufactured by any legitimate pharmaceutical company; and		
	Whereas, The illicit source of synthetic cannabinoids leads to the potential for contamination with other potentially injurious compounds, with or without the knowledge of the purchasers and users of these drugs; and		
	Whereas, In Illino contaminant (ider antagonist) that h for critical care se	is there have been over 100 persons who have been exposed to a ntified in some of the cases as brodifacoum, a poison that is a vitamin K has resulted in a severe bleeding diathesis leading to hospitalization, the need ervices, and a number of deaths; and	
	Whereas, While r sought care from United States; the	nearly all of these patients so far have been in the state of Illinois and have Illinois physicians, there is potential for this to occur in other places across the erefore be it	
	RESOLVED, Tha of the adverse ps related to the use Policy); and be it	t our American Medical Association encourage all physicians to become aware ychiatric and medical effects, including coagulopathy with severe bleeding, of synthetic cannabinoids, which may or may not be contaminated (New HOD further	
34 35 36	RESOLVED, Tha cannabinoids and risks that can pro	It our AMA encourage physicians to educate their patients about synthetic I strongly advise them that the use of these drugs carries significant health duce psychiatric morbidity and hematological mortality. (New HOD Policy)	
	Fiscal Note: Minir	nal - less than \$1,000.	

Resolution: 513 (A-18)

	Introduced by:	Illinois	
	Subject:	Hand Sanitizer Effectiveness	
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)	
1 2 3	Whereas, Under current regulations, manufacturers can make wide-ranging claims about their products' effectiveness in killing germs; and		
3 4 5 6	Whereas, Chemicals used in hand sanitizers may affect the reproductive system or the production of hormones; and		
6 7 8 9 10 11 12 13 14 15 16 17 18	Whereas, The National Institute of Occupational Safety and Health maintains that washing with soap and water is the most effective way to kill germs; and		
	Whereas, The U.S. Food and Drug Administration is undertaking a review of health care and consumer antiseptic rubs and wash products, and final rules on both health care and consumer antiseptic rubs were issued in 2017 determining that certain active ingredients used in antiseptic products are not generally recognized as safe and effective; therefore be it		
	RESOLVED, That our American Medical Association urge the U.S. Food and Drug Administration and the Centers for Disease Control and Prevention to continue to study the use of hand sanitizers in clinical settings, including the risks and benefits to patients and health care professionals. (Directive to Take Action)		
	Fiscal Note: Mode	est - between \$1,000 - \$5,000.	

Resolution: 514 (A-18)

	Introduced by:	Michigan	
	Subject:	Effects of Virtual Reality on Human Health	
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)	
$\begin{array}{c}1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\11\\2\\13\\14\\15\\6\\7\\8\\9\\0\\12\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\2\\$	Whereas, Virtual real life exposure	reality offers realistic sensory experience that humans can interpret similarly to <sup>1</sup> ; and	
	Whereas, Public of headsets sold in 2	consumption of virtual reality is increasing, with one million virtual reality 2017 and 13.7 million expected in 2018 <sup>2</sup> ; and	
	Whereas, Children from ages 6-18 experience virtual reality as more vivid and real than those over the age 18, describing it as salient, immersive and similar to reality <sup>3</sup> ; and		
	Whereas, Gaming disorder, defined as impaired control over gaming and greater prioritization of gaming over other activities, may be included on the 11th Revision of the International Classification of Disease (ICD-11) <sup>4</sup> ; and		
	Whereas, Interne the population wit	t gaming disorder alone is estimated at impacting on average 4.7 percent of h studies ranging from 0.7-15.6 percent <sup>5</sup> ; and	
	Whereas, Virtual disorder <sup>6</sup> , ethical risks, including th sense of reality <sup>8</sup> ;	reality raises concerns for mental health risks such as depersonalization risks about the use of personal data and personal privacy <sup>6,7</sup> , and physical e risk of falls and injuries associated with spatial movement affected by altered and	
	Whereas, Despite in treating certain rehabilitation <sup>9,10,17</sup>	e these risks, current research has elucidated potential benefits of virtual reality disorders, including alcohol dependence, psychosis, and stroke <sup>1</sup> ; and	
26 27 28	Whereas, As it cuphysical, cognitive	irrently stands, limited research exists on the effects of virtual reality on e, and social development of children and adolescents <sup>9,12</sup> ; and	
29 30 31 32	Whereas, Our AMA rejects the excessive portrayal of violence in various entertainment media, including videos and computer games, while encouraging the depiction of its medical consequences (H-515.974); and		
3∠ 33 34 35	Whereas, Our AM video game and i effects (H-60.915	A supports heightened awareness of the need for monitoring and restricting of nternet use, related but distinct from virtual reality, to limit negative health ); therefore be it	
37 38	RESOLVED, Tha virtual reality on h	t our American Medical Association support further study on the impact of numan health. (New HOD Policy)	

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

Received: 05/02/18

## **RELEVANT AMA POLICY**

#### Mass Media Violence and Film Ratings H-515.974

Redressing Shortcomings in the Current System: The AMA: (1) will speak out against the excessive portrayal of violence in the news and entertainment media, including newscasts, movies, videos, computer games, music and print outlets, and encourage the depiction of the medical, social and legal consequences of violence by the media;

(2) advises physicians to counsel parents about the known effects of media violence on children's behavior and encouraging them to reduce the amount of violent programming viewed by their children;

(3) monitors changes in the current ratings system and working through state medical societies to inform physicians and their patients about these changes; and

(4) supports all other appropriate measures to address and reduce television, cable television, and motion picture violence.

Citation: (BOT Rep. 18, A-94; Modified: Res. 417, I-95; Appended: Sub. Res. 419, A-98; Modified and Reaffirmed: CSAPH Rep. 2, A-08; Reaffirmation A-13)

#### Emotional and Behavioral Effects of Video Game and Internet Overuse H-60.915

Our AMAsupports increased awareness of the need for parents to monitor and restrict use of video games and the Internet and encourage increased vigilance in monitoring the content of games purchased and played for children 17 years old and younger. Citation: CSAPH Rep. 01, A-17;

<sup>&</sup>lt;sup>1</sup> Gega, L. The virtues of virtual reality on in exposure therapy, Apr 2017. Br J Psychiatry, 210(4), pp. 245-246.

<sup>&</sup>lt;sup>2</sup> Lamkin, P. Virtual reality headset sales hit 1 million, Nov 30, 2017. Forbes Magazine.

<sup>&</sup>lt;sup>3</sup> Bailey, J and Bailenson, J. Immersive virtual reality and the developing child, Jul 14, 2017. Cog Dev Digital Contexts, pp. 181-200. <sup>4</sup> Gaming disorder, Jan 2018. World Health Organization. http://www.who.int/features/qa/gaming-disorder/en/

<sup>&</sup>lt;sup>5</sup> Feng, W., Ramo, D., Chan, S., and Bourgeois, J. Internet gaming disorder: trends in prevalence 1998-2016, Dec 16, 2016. Addictive Behaviors, 75, pp. 17-24.

<sup>&</sup>lt;sup>6</sup> Spiegel, J. The ethics of virtual reality technology: social hazards and public policy recommendations, Sep 23, 2017. Sci Eng Ethics.

<sup>&</sup>lt;sup>7</sup> O'Brolchain, F., Jacquemard, T., Monaghan, D., O'Connor, N. Novitzky, P. and Gordijn, B. The convergence of virtual reality and social networks: threats to privacy and autonomy, Feb 2016. Sci Eng Ethics, 22(1), pp. 1-29.

<sup>&</sup>lt;sup>8</sup> La Motte, S. The very real health dangers of virtual reality, Dec 13, 2017. CNN.

<sup>&</sup>lt;sup>9</sup> Son, J., Lee, S., Seok, J., Kee, B., Lee, H., Kim, H., Lee, T., and Han, D. Virtual reality therapy for the treatment of alcohol dependence: a preliminary investigation with positron emission tomography/computerized tomography, Jul 2015. J. Stud Alcohol Drugs, 76(4), pp. 620-627.

<sup>&</sup>lt;sup>10</sup> Rus-Calafell, M., Garety, P., Sason, E., Craig, T., and Valmaggia, L. Virtual reality in the assessment and treatment of psychosis: a systematic review of its utility, acceptability and effectiveness, Feb 2018. Psych Med, 48(3), pp. 362-391.

<sup>&</sup>lt;sup>11</sup> Saposnik, G. and Levin, M. Virtual reality in stroke rehabilitation: a meta-analysis and implications for clinicians, May 2011. Stroke, 42(5), pp. 1380-1386.

<sup>&</sup>lt;sup>12</sup> Park, S., Kim, S., Roh, S., Soh, M., Lee, S., Kim, H., Lee, Y., and Han, D. The effects of a virtual reality treatment program for online gaming addiction, Jun 2016. Comput Methods Programs Biomed, 129, pp. 99-108.

Resolution: 515 (A-18)

	Introduced by:	Michigan	
123456789011234567890112345678901123456789011234567890112223245223452234522345222345222345222345222345222345222345222234522223452222345222234522222222	Subject:	Information Regarding Animal-Derived Medications	
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)	
	Whereas, In one study, 84 percent of the patients surveyed reported that they were not aware that several medications contained ingredients derived from pork and/or beef; and		
	Whereas, Approx patients wanted th inform them wher	imately 63 percent of patients wanted their physicians, and 35 percent of the heir non-physician health care providers (e.g., pharmacists, nurses, etc.), to using such medications <sup>1</sup> ; and	
	Whereas, In the same study, approximately 70 percent of physicians were unaware that several medications contain ingredients that might be against their patients' religion, and 70 percent thought that it was important to inform their patients if such drugs were prescribed <sup>1</sup> ; and		
	Whereas, The animal origin of some drugs may not always be known to staff prescribing or administering these drugs <sup>2</sup> ; and		
	Whereas, A pilot study suggests that both patients and physicians think that patients should be informed whenever medications that contain pork- and/or beef-derived products are prescribed <sup>1</sup> ; and		
	Whereas, In a mu awareness of pati prescribing <sup>3</sup> ; and	Ilticultural context, it is essential that prescribers have a minimal level of ients' religious sensitiveness so that these can be considered when	
	Whereas, In one s beef products mig gelatin and/or ste	study, patients with religious prohibitions against consumption of pork and/or ght stop their medications when prescribed those with pork- and beef-derived aric acid <sup>4</sup> ; therefore be it	
20 27 28 29 30	RESOLVED, Tha awareness pertain prescription option	t our American Medical Association support efforts to improve cultural ning to the use of animal-derived medications when considering different ns (New HOD Policy); and be it further	
30 31 32 33	RESOLVED, Tha available to the pu ingredients derive	t our AMA encourage the U.S. Food and Drug Administration to make ublic an easily accessible database that identifies medications containing ed from animals. (Directive to Take Action)	
	Fiscal Note: Mode	est - between \$1,000 - \$5,000.	

 <sup>&</sup>lt;sup>1</sup> Sattar SP, Ahmed MS, Madison J, et al. Patient and Physician Attitudes to Using Medications with Religiously Forbidden Ingredients. Ann Pharmacother. 2004;38(11):1830-1835. doi:10.1345/aph.1E001.
 <sup>2</sup> Newson AJ. Clinical Ethics Committee Case 9: Should we inform our patient about animal products in his medicine? Clin Ethics.

 <sup>&</sup>lt;sup>2</sup> Sattar SP, Ahmed MS, Majeed F, Petty F. Inert Medication Ingredients Causing Nonadherence Due to Religious Beliefs. Ann

Pharmacother. 2004;38(4):621-624. doi:10.1345/aph.1D324.

Resolution: 516 (A-18)

	Introduced by:	Michigan	
	Subject:	Waste Incinerator Ban	
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)	
$\begin{array}{c}1\\2\\3\\4\\5\\6\\7\\8\\9\\10\\1\\12\\14\\15\\16\\17\\18\\19\end{array}$	Whereas, The ide electricity originat	ea to increase the use of trash incinerators to produce heat/steam to generate ed during an energy crisis during the Nixon administration; and	
	Whereas, As part largest municipal opposition; and	of a financial decision in the 1970s, the city of Detroit decided to create the solid waste incinerator in the nation, but this was not without controversy and	
	Whereas, It required about \$440 million in bond sales to create the Detroit incinerator and it was hypothesized that the cost of waste collection services would be offset by revenue generated from the sale of steam and electricity; and		
	Whereas, Health experts and environmentalists in southeast Michigan and southwestern Ontario even at the time opposed constructing this facility since it would put millions of tons of pollutants into the air that would increase morbidity rates; and		
	Whereas, The inc State of Michigan when the facility a	inerator became operational in 1986, and due to the increase in pollution, the 's Department of Environment Quality required expensive new pollution control applied for permit renewals in 1991; and	
20 21 22 23	Whereas, Due to financial holding of finance the new e	a lack of funds to install this equipment, the City of Detroit sold the facility to companies for \$54 million and the company issued bonds for \$157 million to equipment; and	
23 24 25	Whereas, These I	bonds were still being paid by the city until 2009; and	
26 27 28	Whereas, The firm and	ns also received pollution tax credits worth about \$200 million for the upgrade;	
29 30 31	Whereas, \$4.1 mi directors for opera	illion dollars in Brownfield tax credits are given to the incinerator's board of ation; and	
32 33 34	Whereas, The trad dwindled and the	sh base for the city of Detroit has dwindled as the population of Detroit has facility began importing trash from neighboring areas to stay operational; and	
35 36 37	Whereas, Oaklan produced 19 perc neighboring areas	d County was responsible for 66 percent of the waste, while Wayne County ent, leading to injustice as individuals in Detroit bear the health effects of s' trash; and	

1 Whereas, In 2007-2008, City of Detroit residents were being charged about \$172 per ton of 2 trash, which is five to seven times the cost per ton offered to neighboring areas and 14 times the 3 cost per ton offered to private haulers; and 4 5 Whereas, The incinerator is currently operated by the Michigan Waste Energy firm, a subsidiary 6 of Covanta Energy, and due to environmental regulations, they are restricted to burning two of 7 the three furnaces at one time amounting to approximately 2,800 tons of trash daily or 800,000 8 tons of trash yearly; and 9 10 Whereas, It is not financially beneficial to run the facility because the city of Detroit pays more 11 per ton to dispose of solid waste in this manner than our surrounding communities or other large 12 cities spend in disposing of their solid waste using other methods; and 13 14 Whereas, Detroit pays \$125 per ton to get rid of municipal solid waste via the incinerator as 15 compared to \$25 per ton to dispose in local landfills; and 16 17 Whereas, Generated steam and electricity are sold to Michigan Consolidated Gas/Detroit 18 Edison for \$40 million annually; and 19 20 Whereas, The facility is one of the state's leading producers of pollution producing 25 tons of 21 hazardous air pollutants annually as well as 1800 tons of sulfur dioxide, nitrous oxide, mercury 22 and lead; and 23 24 Whereas: The incinerator creates around 25 tons of hazardous wastes every year and over 25 1800 tons of pollutants; and 26 27 Whereas, The ash of slag byproducts of the incinerator are toxic and disposed into landfills; and 28 29 Whereas, Michigan landfills abide by both federal and stringent state regulations regarding 30 liners and general standards to prevent environmental contamination; and 31 32 Whereas, An inconsistency exists where individuals in the State of Michigan are banned from 33 burning trash under the Public Act 102 of 2012 and open burning is regulated under the Natural 34 Resources and Environmental Protection Act (Act 451 of 1994), yet facilities such as the 35 incinerator are exempt from such acts; and 36 37 Whereas, There is concern for those employed by the facility, but recycling and composting 38 create four to ten times more jobs than landfills or incinerators; and 39 40 Whereas, Recycling and composting could be made widespread, the presence of the incinerator 41 and those that are financially invested and profit from the facility continue to prevent taking 42 steps away from depending on this facility; and 43 44 Whereas, Currently only 11 percent of the city of Detroit residents participate in recycling; and 45 46 Whereas, According to the Environmental Protection Agency (EPA), burning municipal solid 47 waste creates nitrogen oxides, sulfur dioxides, mercury and dioxins along with the primary 48 greenhouse gas, carbon dioxide even after using modern scrubbing equipment; and

1 Whereas, It is well known that asthma rates are higher in Detroit as compared to the average 2 rate in the rest of the state, it is important to note that asthma hospitalization rates are 3 approximately three times that of the Michigan average for children living around the incinerator: 4 and 5 6 Whereas, Data from the EPA in 2009 cited that from 1990 to 2003 asthma hospitalization rates 7 were 75 percent higher in Wayne County than in the rest of the State of Michigan; and 8 9 Whereas, Hospital and health care costs of individuals affected by the pollution from the facility 10 add to the cost burden of the facility; and 11 12 Whereas, The Great Lakes Environmental Law Center obtained information using the Freedom 13 of Information Act, citing the facility for violating the clean air act (21 violations since 2015 for 14 strong odors and 19 violations for carbon monoxide, sulfur dioxide, and particulate matter 15 emissions above allowable limits); and 16 17 Whereas, Pollutants from the facility are known to cause cardiac disease, premature death, and 18 premature birth all of which are higher in Detroit along with causing irritation to mucous 19 membranes including the eyes, ear, nose, and throat; and 20 21 Whereas, According to EPA statistics 7,280 residents live within one mile of the facility and 22 these residents suffer from respiratory related health issues; and 23 24 Whereas, In 2007 approximately 14 percent of the nation's solid waste was burned in 89 25 incinerators around the country they only produced 3/1000 of the nation's electricity and 26 currently there are between 80 to 90 facilities in the U.S. that are still operational; and 27 28 Whereas, In the State of Michigan there are two trash burning facilities, one in Detroit and the 29 other in Kent county; and 30 31 Whereas, At the current rate of deposition, Michigan has an estimated 27 years of landfill space 32 available, our state currently imports 22.7 percent of yearly waste deposition from other states 33 and countries; and 34 35 Whereas, Current yearly estimates of 0.16 percent of landfill waste originate from incinerator by-36 products, if all the incinerator waste was directed away from the incinerators and instead toward 37 landfills without recycling or composting, it would only amount to 1.8 percent of yearly landfill 38 waste; and 39 40 Whereas, The approach to dealing with waste currently directed toward incinerators could include a combination of reducing waste production, recycling, composting, and landfill usage 41 42 as well as stopping the practice of importing trash from other states and nations; therefore be it

- 1 RESOLVED, That our American Medical Association amend policy H-135.939 by addition to 2 read as follows:
- 3
- 4 Green Initiatives and the Health Care Community H-135.939
- 5 Our AMA supports and shall prioritize: (1) responsible waste management and clean energy
- 6 production policies that do not pose health risks, including the promotion of appropriate
- 7 recycling and waste reduction; (2) the use of ecologically sustainable products, foods, and
- 8 materials when possible; (3) the development of products that are non-toxic, sustainable, and
- 9 ecologically sound; (4) building practices that help reduce resource utilization and contribute
- 10 to a healthy environment; and (5) community-wide adoption of 'green' initiatives and activities
- 11 by organizations, businesses, homes, schools, and government and health care entities
- 12 (Modify Current HOD Policy); and be it further
- 13
- 14 RESOLVED, That our American Medical Association request and actively advocate for national
- 15 legislation that bans waste incinerators in our nation due to their adverse health effects,
- 16 negative environmental impact, and lack of cost effectiveness. (Directive to Take Action)

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

Received: 05/02/18

#### See AMA Policies:

Pollution Control and Environmental Health H-135.996 Green Initiatives and the Health Care Community H-135.939 Conservation, Recycling and Other "Green" Initiatives G-630.100 Stewardship of the Environment H-135.973

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Resolution: 517 (A-18)

	Introduced by:	Michigan	
	Subject:	Impact of Natural Disasters on Pharmaceutical Supply and Public Health	
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)	
1 2 3 4 5 6	Whereas, In 2017, multiple hurricanes impacted islands in the Caribbean, resulting in direct and indirect damages through destruction of property and loss of municipal power; and		
	Whereas, Recove today; and	ery in those impacted areas has been slow, with several still without power	
7 8 9	Whereas, There is a concentration of pharmaceutical manufacturing in the Caribbean, notably on the island of Puerto Rico, from which the United States receives a significant amount of intravenous fluids and other medications; and		
10 11 12 13 14 15 16 17 18	Whereas, Hospitals and pharmacies in the United States have seen a shortage of these products, with many shortages expected to continue to worsen further before they improve; therefore be it		
	RESOLVED, That our American Medical Association study the impact of natural disasters on the pharmaceutical supply chain and downstream effects on patient care, as well as the adequacy of our governmental response to mitigating these recent natural disasters (Directive to Take Action); and be it further		
19 20 21 22	RESOLVED, That read as follows:	t our American Medical Association amend policy H-100.956 by addition to	
22 23 24 25 26 27 28 29 30 31 32 33 34 35 36 37 38	National Drug Shortages H-100.956 1. Our AMA supports recommendations that have been developed by multiple stakeholders to improve manufacturing quality systems, identify efficiencies in regulatory review that can mitigate drug shortages, and explore measures designed to drive greater investment in production capacity for products that experience drug shortages, and will work in a collaborative fashion with these and other stakeholders to implement these recommendations		
	<ol> <li>Our AMA supports authorizing the Secretary of Health and Human Services to expedite facility inspections and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.</li> <li>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.</li> </ol>		

- 4. The Council on Science and Public Health shall continue to evaluate the drug shortage
   issue, including the impact of group purchasing organizations on drug shortages, and report
   back at least annually to the House of Delegates on progress made in addressing drug
   shortages.
- 5. Our AMA urges the development of a comprehensive independent report on the root
  causes of drug shortages. Such an analysis should consider federal actions, the number of
  manufacturers, economic factors including federal reimbursement practices, as well as
- 8 contracting practices by market participants on competition, access to drugs, and pricing. In
- 9 particular, further transparent analysis of economic drivers is warranted. The Centers for
- Medicare & Medicaid Services should review and evaluate its 2003 Medicare reimbursement
   formula of average sales price plus 6% for unintended consequences including serving as a
   root cause of drug shortages.
- 6. Our AMA urges regulatory relief designed to improve the availability of prescription drugs
  by ensuring that such products are not removed from the market due to compliance issues
  unless such removal is clearly required for significant and obvious safety reasons.
- 16 7. Our AMA supports the view that wholesalers should routinely institute an allocation system
- that attempts to fairly distribute drugs in short supply based on remaining inventory and
   considering the customer's purchase history.
- 8. Our AMĂ will collaborate with medical specialty partners in identifying and supporting
   legislative remedies to allow for more reasonable and sustainable payment rates for
   prescription drugs.
- 9. Our AMA urges that during the evaluation of potential mergers and acquisitions involving
- pharmaceutical manufacturers, the Federal Trade Commission consult with the FDA to
   determine whether such an activity has the potential to worsen drug shortages. (Modify
- 25 Current HOD Policy)

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

Resolution: 518 (A-18)

Introduced by:	Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island, Vermont
Subject:	Portable Listening Devices and Noise Induced Hearing Loss
Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)

1	Whereas, Portable listening devices have been replaced by explosive growth of cellular
2	telephones which can produce even higher sound levels; and
3 1	Whereas The growth in cellular has occurred across a wide population demographic. It has
5	correlated with wider use of earbuds in adolescents and young adults in particular: and
6	······································
7	Whereas, The popularity of cell phones has resulted in greater daily use of earbuds increasing
8	the potential for hearing loss; and
9	
10	Whereas, Some manufacturers have developed earbuds which limit the maximum sound
11	produced reducing the risk of hearing loss; and
12	
13 14	Whereas, Many manufacturers still produce earbuds without that technology thus raising the risk of hearing loss; therefore be it
15	
16	RESOLVED, That our American Medical Association update its policy on portable listening
17	devices to support the use of portable listening devices that limit the maximum sound amplitude
18	to safe levels (New HOD Policy); and be it further
19	
20	RESOLVED That our AMA advocate on a federal level for labeling on earbuds that do not have
21	amplitude limiters to warn of the risk of hearing loss with extended use at high volume levels for
22	extended periods as described in Council on Scientific Affairs Report 6-A-08. (New HOD Policy)

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

Resolution: 519 (A-18)

	Introduced by:	Maryland	
	Subject:	Warning Labels for Children's Digital and Video Games	
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)	
1 2 3	Whereas, MedChi in 2005 adopted a resolution asking that the AMA study the behavioral effects of video games including the potential for being addictive and possibly including warning labels on them if there was evidence of this; and		
5 6 7 8	Whereas, The Council on Science and Public Health in response to the MedChi resolution reviewed the literature and reported to the HOD at the 2007 Annual Meeting that there was evidence of "over use" by a small portion of the population with was estimated at 10- 15% of players; and		
9 10 11 12	Whereas, The report recommended further study and in the APA DSM 5 (2013) Internet Gaming Disorder was a condition recommended for further study; and		
12 13 14 15 16	Whereas, <i>AMA Morning Rounds</i> and <i>APA Headline News</i> both reported that the World Health Organization added "gaming disorder" to its list of mental health conditions" in ICD-11 in 2018; and		
17 18 19	Whereas; There a same addiction po susceptible to this	are some video games that can be used educationally and do not have the otential as others, those with violence are often the ones that are most and are heavily marketed by the industry; and	
20 21 22	Whereas, Many o	f the video games are especially targeted to children; and	
23 24 25	Whereas, Children's first and often only exposure to high power rapid firing weapons of war is often through video games; and		
26 27 28	Whereas, The Arr having targets in t	ny uses similar means to desensitize soldiers to killing enemy soldiers by he shape of human beings; and	
29 30	Whereas, The hu	man brain is still developing well into the twenties; therefore be it	
31 32 33 34 35 36	RESOLVED, That digital and video g children this can b more important de escalate despite t occur when attem	t our American Medical Association advocate for putting warning labels on games, warning parents to monitor children's use and be aware that for some become habit forming, leading to increased time spent on gaming at the cost of evelopmental issues, take precedence over other aspects of their life and he occurrence of negative consequences and withdrawal symptoms may opts are made to reduce or stop it. (Directive to Take Action)	

Fiscal Note: Minimal - less than \$1,000. Received: 05/08/18

Resolution: 520 (A-18)

Introduced by:	American Urological Association, American Association of Clinical Urologists, American Academy of Dermatology, American Society for Dermatologic Surgery Association, American Society of Dermatopathology, Society for Investigative Dermatology, American College of Mohs Surgery
Subject:	Handling of Hazardous Drugs
Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)

1 Whereas, There is a flurry of regulatory and legislative activities to mandate the guidance 2 outlined in the current revision of General Chapter <800> Hazardous Drugs<sup>1</sup> – Handling in 3 Healthcare Settings in the United States Pharmacopeia (USP) Compounding Compendium; and 4 5 Whereas, The official date of implementation of Chapter <800> is December 1, 2019; and 6 7 Whereas, In Chapter <800>, USP refers to the National Institute for Occupational Safety and 8 Health (NIOSH) list<sup>2</sup> of hazardous drugs for required handling guidelines and specifically 9 identifies several therapeutic drugs for the treatment of bladder, kidney and prostate cancers 10 currently prepared and administered in the physician's office as antineoplastics; and 11 12 Whereas, There is limited or no risk of exposure/harm to health care providers/workers in the 13 manner in which these therapeutic drugs are currently prepared in the physicians' office; and 14 15 Whereas, Because of these agent's designation as antineoplastics, they are considered 16 hazardous and Chapter <800> requires the use of a containment primary engineering control (C-PEC) ventilated device designed to minimize worker and environmental exposure, a 17 18 containment secondary engineering control (C-SEC) room where the C-PEC is placed and 19 Closed System Transfer Devices (CSTD), such as a hood, and personal protective equipment 20 for handling of hazardous drugs; and 21 22 Whereas, Facilities required to adhere to Chapter <800> Hazardous Drugs must also follow 23 guidelines outlined in General Chapter <795> Pharmaceutical Compounding<sup>3</sup> – Nonsterile 24 Preparations and General Chapter <797> Pharmaceutical Compounding – Sterile Preparations. 25 New revisions to Chapters <795> and <797> include reference "must comply with Hazardous 26 Drugs - Handling in the Healthcare Settings (800)"; and

<sup>&</sup>lt;sup>1</sup> General Chapter <800> describes practice and quality standards for the handling of hazardous drugs to promote patient safety, worker safety, and environmental protection of healthcare personnel.

<sup>&</sup>lt;sup>2</sup> NIOSH identified hazardous drugs in three groups: Table 1 Antineoplastic drugs including antineoplastic drugs with special handling information, Table 2 Non antineoplastic drugs with special handling instructions and Table 3 Non-antineoplastic drugs that primarily have adverse reproductive effects. NIOSH has a draft document Policy and Procedures for Developing NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings that outlines how drugs are selected to be included on the NIOSH list and how they determine the drugs to be hazardous.

<sup>&</sup>lt;sup>3</sup> These chapters are undergoing revisions this year to provide a unified approach to quality compounding. Chapter <795> was open for public comment ending in April 2018 and <797> will be available in July 2018.

Whereas, The Food & Drug Administration's (FDA)<sup>4</sup> does not consider compounding of a drug if 1 it is reconstituted according to manufacturers' recommendations. General Chapter <795> 2 3 defines nonsterile preparations as "nonsterile compounding is defined as combining, admixing, 4 diluting, pooling, reconstituting other than as provided in the manufacturer package insert, or 5 otherwise altering a drug or bulk drug substance to create a nonsterile medication. 6 Reconstituting a conventionally manufactured nonsterile product in accordance with the 7 directions contained in the approved labeling provided by the product's manufacturer is not

8 considered compounding as long as the product is prepared for an individual patient and not

9 stored for future use." This should apply to all preparations if there are no special instructions

10 from the manufacturer; and

11

12 Whereas, These regulations will negatively impact provision of cancer treatments to patients. The costs to physician practices required to install hoods and ventilation systems in their offices 13 14 is prohibitive. In many instances, the installations are not physically possible in the facilities

15 where the practices are located. In most communities, there are not sufficient alternative

16 facilities that can meet the C-PEC, C-SEC, and CSTD required for reconstitution or mixing prior

17 to administration of the drugs included in the NIOSH list, leaving the majority of patients without

18 access to the therapeutics they require; and

19

20 Whereas, Access to care is prohibitive/hinders access to the full range of treatments for prostate

and bladder cancer for urologic patients if General Chapter <800> must be adhered to; 21 22 therefore be it

23

24 RESOLVED, That our American Medical Association work with United States Pharmacopeia to

25 revisit the requirements in General Chapter <800> of the USP Compounding Compendium and

26 review Chapters <795> and <797> to ensure that the requirements included in those chapters

are not onerous to physicians and prohibitive to their current ability to provide medications to 27

28 their patients. (Directive to Take Action)

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

Received: 05/10/18

#### **RELEVANT AMA POLICY**

#### Protect Individualized Compounding in Physicians' Offices as Practice of Medicine H-120.929

Our AMA will advocate that the US Food and Drug Administration remove physician offices and ambulatory surgery centers from its definition of a compounding facility.

USP Compounding Rules H-120.930

1. Our AMA will engage in efforts to convince United States Pharmacopeia (USP) to retain the current special rules for procedures in the medical office that could include but not be limited to allergen extract compounding in the medical office setting and, if necessary, engage with the U.S. Food and Drug Administration (FDA) and work with the U.S. Congress to ensure that small volume physician office-based compounding is preserved.

2. Our AMA will undertake to form a coalition with affected physician specialty organizations such as allergy, dermatology, immunology, otolaryngology, oncology, ophthalmology, neurology, and rheumatology to jointly engage with USP, FDA and the U.S. Congress on the issue of physician office-based compounding preparations and the proposed changes to USP Chapter 797.

3. Our AMA reaffirms that the regulation of compounding in the physician office for the physician's patients be under the purview of state medical boards and not state pharmacy boards.

4. Our AMA supports the current 2008 USP Chapter 797 sterile compounding rules as they apply to allergen extracts, including specifically requirements related to the beyond use dates of compounded allergen extract stock. Citation: Res. 204, A-16; Reaffirmation: A-17

See also: USP Compounding Rules H-120.930; Appropriate Use of Compounded Medications in Medical Offices H-120.934; Opposition to USP 800 D-120.941; Pharmacy Compounding H-120.945; Access to In-Office Administered Drugs H-330.884

<sup>&</sup>lt;sup>4</sup> Personal communication, Food and Drug Administration (Compounding) to AUA.

	Introduced by:	American Thoracic Society, American College of Chest Physicians	
	Subject:	EPA Glider Truck Standard	
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)	
1 2 3	Whereas, Air pollupollution emission	ution emissions from diesel truck engines are an important source of air is in the U.S.; and	
4 5 6	Whereas, Reducing quality and reduce	ng air pollution emissions from diesel engines in the U.S. will improve air adverse health effects associated with air pollution; and	
0 7 8	Whereas, The U.s diesels truck engi	S. Environmental Protection Agency (EPA) has established emissions for new nes that significantly reduce emissions compared to older diesel engines; and	
9 10 11	Whereas, An industry has developed, known as the glider kit industry, that reconditions old diesel truck engines, installs them in new chassis and sells these trucks as "new"; and		
12 13	Whereas, These '	'new" glider kits do not meet emissions standards for new diesels trucks; and	
14 15 16	Whereas, The EP emissions than di	A's internal research shows glider kit diesel engines emit 40-50 times more esel trucks that meet the new diesel truck emissions standard; and	
17 18 19	Whereas, In 2016 that evade new di	s, the EPA issued final rules to limit the number of glider kits that can be sold esel engines emissions standards; and	
20 21 22 23 24	Whereas, In 2017 dramatically expa new diesel engine	, the EPA issued a proposed rule to repeal limits on glider trucks – nding the number of glider kit diesel engines that can be sold that do not meet e emissions standard; and	
24 25 26 27 28 20	Whereas, In provi on a non-peer rev industry and that disease engines)	ding a justification repealing the limits on Glider Kits, the EPA relied, in part, riewed study conducted at Tennessee Tech that was paid for by the glider kit study findings (that glider kits engines have emissions comparable to new have since come under question; and	
29 30 31 32 23	Whereas, If the ro will comprise 5 pe truck emissions; t	Il back of glider kit roll is implemented, it is estimated in year 2025 glider kits ercent of the U.S. diesel truck vehicle fleet but will emit 1/3 of all U.S. diesel herefore be it	
34 35 36 37	RESOLVED, Tha Protection Agency Rule" which would do not meet curre	t our American Medical Association send a letter to U.S. Environmental y (EPA) Administrator opposing the EPA's proposal to roll back the "Glider Kit d effectively allow the unlimited sale of re-conditioned diesel truck engines that int EPA new diesel engine emission standards. (Directive to Take Action)	

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

Received: 05/10/18

## **RELEVANT AMA POLICY**

#### **Reducing Sources of Diesel Exhaust D-135.996**

Our AMA will:

(1) encourage the US Environmental Protection Agency to finalize the most stringent feasible standards to control pollutant emissions from both large and small non-road engines including construction equipment, farm equipment, boats and trains;

(2) encourage all states to continue to pursue opportunities to reduce diesel exhaust pollution, including reducing harmful emissions from existing diesel; and

(3) call for all trucks traveling within the United States, regardless of country of origin, to be in compliance with new diesel emissions standards promulgated by US EPA.

Res. 428, A-04 Reaffirmed in lieu of Res. 507, A-09 Reaffirmation A-11 Reaffirmation A-14

	Introduced by:	American Thoracic Society, American College of Chest Physicians	
$\begin{array}{c}1&2&3&4&5&6\\7&8&9&10&1&1\\1&1&3&1&4&5\\2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2&2&2&2&2\\2&2&2&2&2&2&2&2&2&2&2&2&2\\2&$	Subject:	Silence Science: EPA Proposed Data Policy	
	Referred to:	Reference Committee E (Douglas W. Martin, MD, Chair)	
	Whereas, The Journal of the American Medical Association has published seminal research documenting the adverse human health effects associated with exposure to environmental pollution; and		
	Whereas, Journal articles published in peer-reviewed science journals have provided researchers, clinicians and policy makers critical information on the health effects of environmental exposures; and		
	Whereas, Federal agencies, including the U.S. Environmental Protection Agency (EPA), have relied on the peer review process of scientific and medical journals to provide scientifically reliable information to help share public policy; and		
	Whereas, The EPA has issued a proposed rule that, if implemented, would exclude many seminal peer review journal considerations from consideration by EPA during the policy making process; and		
	Whereas, Remov undermine the sc	ing valid scientific publications from the EPA's policy making process will ience-basis for EPA environmental policy, therefore be it	
	RESOLVED, That our American Medical Association submit comments during the public comment period, or join comments written by other medical organizations, to express concern with the U.S. Environmental Protection Agency's (EPA) proposal to limit the use of research studies published in peer reviewed scientific journals that describe the adverse health effects of exposure to air pollution and other environmental exposures (Directive to Take Action); and be it further		
20 27 28 29 30	RESOLVED, Tha sending a letter to reviewed journals (Directive to Take	t our AMA reaffirm the value and integrity of the journal peer review process by the EPA stating that studies that have been published in scientific peer should be used by the agency in informing EPA regulatory policy making. Action)	
	Fiscal Note: Minir	nal - less than \$1,000.	

## **RELEVANT AMA POLICY**

#### E-7.1.3 Study Design & Sampling

To be ethically justifiable, biomedical and health research that involves human subjects must uphold fundamental principles of respect for persons, beneficence, and justice. These principles apply not only to the conduct of research, but equally to the selection of research topics and study design.

Well-designed, ethically sound research aligns with the goals of medicine, addresses questions relevant to the population among whom the study will be carried out, balances the potential for benefit against the potential for harm, employs study designs that will yield scientifically valid and significant data, and generates useful knowledge. For example, research to develop biological or chemical weapons is antithetical to the goals of the medical profession, whereas research to develop defenses against such weapons can be ethically justifiable.

Physicians who engage in biomedical or health research with human participants thus have an ethical obligation to ensure that any study with which they are involved:

(a) Is consistent with the goals and fundamental values of the medical profession.

(b) Addresses research question(s) that will contribute meaningfully to medical knowledge and practice.

(c) Is scientifically well designed to yield valid data to answer the research question(s), including using appropriate population and sampling controls, clear and appropriate inclusion/exclusion criteria, a statistically sound plan for data collection and analysis, appropriate controls, and when applicable, criteria for discontinuing the study (stopping rules).

(d) Minimizes risks to participants, including risks associated with recruitment and data collection activities, without compromising scientific integrity.

(e) Provides mechanisms to safeguard confidentiality.

(f) Does not disproportionately recruit participants from historically disadvantaged populations or populations whose ability to provide fully voluntary consent is compromised. Participants who otherwise meet inclusion/exclusion criteria should be recruited without regard to race, ethnicity, gender, or economic status.

(g) Recruits participants who lack the capacity to give informed consent only when the study stands to benefit that class of participants and participants with capacity would not yield valid results. In this event, assent should be sought from the participant and consent should be obtained from the prospective participants legally authorized representative, in keeping with ethics guidance.

(h) Has been reviewed and approved by appropriate oversight bodies.

AMA Principles of Medical Ethics: I,II,III,V,VII

The Opinions in this chapter are offered as ethics guidance for physicians and are not intended to establish standards of clinical practice or rules of law. Issued: 2016