Reference Committee K

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12 Information Regarding Animal-Derived Medications

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INTRODUCTION

Resolution 515-A-18, “Information Regarding Animal Derived Medications,” introduced by the Michigan Delegation and referred by the House of Delegates (HOD) asked:

That our American Medical Association (AMA): (1) Support efforts to improve cultural awareness pertaining to the use of animal-derived medications when considering different prescription options. (2) Encourage the U.S. Food and Drug Administration to make available to the public an easily accessible database that identifies medications containing ingredients derived from animals.

Some chemical products used as inactive excipients for prescription drugs, as well as some active prescription medications and also some surgical implants, dressings, and mesh, are derived from animal sources. The consumption or use of such products may be objectionable to certain religions or based on consumer choice. The objective of this report is to summarize the issue and current evidence related to animal-derived components of medical products.

BACKGROUND

Some religious faiths forbid the consumption or use of certain animals and substances derived from them. Additionally, individuals who adhere to a vegetarian or vegan diet may prefer to avoid animal-derived medical products. Individuals who want to avoid animal-derived substances for religious or cultural reasons may inquire about the origin or source of the ingredients in their medical products for informed decision-making regarding treatment with the product. Frequently, however, the information regarding ingredients or composition in medications is difficult to obtain by physicians, pharmacists, and patients.1

Many pharmaceutical products (both active and inactive ingredients used in capsules, tablets, injections, vaccines, creams) and surgical products (implants, wound dressings, surgical mesh) contain ingredients derived from animal sources. Animal-derived ingredients (ADIs) are used in many medical fields and cover an array of products usually at minimal concentrations.1 However, a substantial percentage of patients and physicians are unaware that some medications and medical products contain animal products;2 one survey indicated that 84% of patients and 70% of physicians were unaware that several medications contain ADIs. Additionally, 70% of physicians thought it was important to inform patients who might object if such medications are prescribed.3 Some authors have even suggested obtaining informed consent before using animal-derived products.1
POLICY AND LAW

The U.S. Pharmacopeial Convention is a private, nongovernmental organization that publishes the United States Pharmacopeia (USP) and the National Formulary (NF) as official compendia, collectively called the USP-NF. The Federal Food, Drug and Cosmetic Act (FFDCA) expressly recognizes the USP quality standards for medicines. Although much of the USP-NF is legally enforceable, the USP chapters numbered above <999> are general information and generally do not contain any mandatory requirements, but can include recommendations that may help a firm meet the requirements of current good manufacturing processes (CGMPs) as defined by the U.S. Food and Drug Administration (FDA).

FDA Guidance regarding CGMP includes recommendations and precautions when manufacturing ADIs to ensure that contamination by pathogenic agents does not occur. No guidance regarding labeling of ADIs could be located. Although the FDA does have a database that provides information on inactive ingredients present in FDA-approved drug products, its main purpose is to aid industry in drug development; once an inactive ingredient is part of the formulation for an approved drug product, it is no longer considered new and may require less extensive review when used again. The database includes no information regarding the source of the ingredient.

USP-NF general chapter <7> “Labeling” details the requirements for the labeling of active ingredients in pharmaceutical products. No discussion of ingredient source is included. It is noted, however, that many monographs have unique labeling requirements that should be used consistently. USP-NF informational chapter <1091> “Labeling of Inactive Ingredients” states that all ingredients should be disclosed for all medications. The information can be found on the package or insert of a prescription drug and on the drug facts label on the outside of the box for over-the-counter drugs. No requirement exists for a manufacturer to declare how an ingredient is sourced. Additionally, the Code of Federal Regulations calls for all ingredients to be listed, but inactive ingredients are exempt from provisions on misbranding, including some that relate to false or misleading labeling.

CULTURAL CONSIDERATIONS

Some religious groups avoid products from certain animals and many patients have strong religious convictions and beliefs. Vegetarians do not consume foods either directly obtained or using products from the slaughter of an animal. Vegans do not consume any foods originating from animals.

Several investigators have surveyed worldwide religious leaders for their opinions regarding the acceptability of certain medical products, both medications and surgical implants/dressings/mesh, for their religions. The surveys generally focused on the six largest religions worldwide and reported varied practices. Many Hindus and Sikhs do not approve of the use of bovine- or porcine-derived products and also follow vegetarian diets. Many who practice Islam or Judaism do not accept the use of porcine-derived products. No principle in Buddhism prohibits the use of animal-derived medical products; however, many members of one of the two major branches follow a vegetarian diet. Most Christians, other than those who follow vegetarian or vegan diets, do not have restrictions. Although Jehovah’s Witnesses refuse blood transfusions, all other medical related products and decisions are at the discretion of the patient and physician. Notably, leaders from all surveyed religions stated that the use of animal-derived medical products would be accepted in the absence of any other alternative or in emergency situations. In difficult situations, religious leaders can also be contacted for guidance.
OTHER CONSIDERATIONS

Various communication practices for patient-directed medication information including readability, container labeling (font, format, and organization), information content length, and supplementary medication instructions have been described, but do not address ingredient lists and source.\(^2\)

Reports of medication non-adherence or discontinuation because of ADI avoidance exist.\(^{13}\) Some authors have suggested that when healthcare professionals listen to patients’ cultural beliefs, actively involve them in medication prescribing decisions, and take their views and preferences into account, adherence is more likely.\(^{14}\)

Nevertheless, ADI information is inconsistently reported, difficult to obtain, and sometimes incorrect.\(^2,15\) Also noteworthy is the fact that excipients and inactive ingredients likely differ between branded and generic forms of medications; therefore, knowledge of the ingredients in a particular branded medication will not guarantee knowledge of generic versions. Some drugs, especially those produced in gelatin capsules, may be available in alternative formulations that do not contain ADIs. Literature discussing clinical decision support systems for physicians and drug databases used by pharmacists has not addressed the issue of ADIs and the inclusion of relevant ADI information. If the source of ADIs, or the fact that an ingredient is an ADI, were required labeling for manufacturers, the potential would exist for this information to be included in the datasets used by clinical decision support systems and drug databases downstream.

PROBLEM MEDICAL PRODUCTS

Both active and inactive pharmaceutical ingredients as well as implants, dressings, and mesh used in surgery can contain ADIs. Some of the more common examples of these ADIs are included in discussion below.

Active Ingredients

The following are examples of products that contain an active ingredient derived from an animal source:

- Conjugated estrogens (Premarin) are derived from the urine of pregnant mares.\(^{16}\)
- Low molecular weight heparin is porcine-derived.\(^{17}\)
- Corticotropin is obtained from porcine pituitary gland.\(^{18}\)
- Hyaluronidase is derived from crude extracts of ovine or bovine testicular tissue.\(^{19}\)
- Pancreatin (also known as pancreatic enzymes, pancrelipase) is bovine derived.\(^{20}\)

The product information for these medications indicates that they are animal-derived. However, for some, the information is difficult to locate, often only becoming obvious because of a statement in the “allergy” or “contraindications” section (e.g., This medication is contraindicated in patients with sensitivity to proteins of porcine origin.).

Inactive Ingredients

In a recent review, the use of ADIs in the 100 most commonly prescribed medications in primary care in the United Kingdom found that 74 contained at least one of the three most common excipient ADIs used – gelatin, lactose, and magnesium stearate.\(^{15}\) Of these 74 products, 42 provided no indication of the presence of an ADI, and 2 products incorrectly stated that no animal content was contained in the product.\(^{15}\)
Gelatin is a generic term for a mixture of purified protein fractions obtained by hydrolysis of animal collagen obtained from bovine or porcine bone, or from bovine, porcine, or fish skin. It is most frequently used in the capsules of medications. Due to the demand for gelatin-free medication, the production of vegetarian capsules made from hypromellose has expanded, and the use of bioreactors utilizing “cellular agriculture” to create purified proteins that are assembled into collagen and then made into gelatin is becoming popular; but animal-derived gelatin is still used commonly.2,21

Lactose is a natural disaccharide present in the milk of most mammals and is traditionally extracted from milk using bovine rennet. Some manufacturers now use a vegetarian process instead of bovine rennet to extract lactose from bovine milk, but this has caused confusion about suitability for those who avoid bovine products.15 Lactose is widely used as a filler and diluent in tablets and capsules and is also used as a diluent in dry-powder inhalations, in the preparation of sugar-coating solutions, and in some injections.2,15

Stearic acid, utilized as magnesium stearate in products, is a fatty acid sourced from rendered bovine, porcine, or ovine fat or produced from vegetable matter. It is primarily used as a lubricant in capsule and tablet manufacture and improves the solubility of some medications. If the source of the magnesium stearate is not indicated on a drug label, whether or not it is an ADI is unknown and difficult to determine.2

Vaccines

Materials used in the production of some vaccines, e.g., excipients or nutritional supplements for cell cultures, are ADIs. These include gelatin, trypsin (usually bovine sourced), and bovine serum or albumin.22 Religious scholars distinguish between the use of ADIs in oral or non-oral medications and have issued rulings or waivers that allow use of non-oral medications containing ADIs, such as vaccines.2 Despite this distinction, reports persist of concern with ADIs in vaccines.15

Surgical Sutures, Implants, Dressings, and Mesh

The use of synthetic and biological products is widespread in surgeries, and the use of a biologic product that is prohibited or is sacred in a surgical setting is a concern.8,10 Sutures used to close wounds or surgical incisions can contain animal-derived ingredients. A recent study confirmed the frequent use of ADIs, such as collagen membrane, collagen gel, fibrin glue, fibrinogen, aprotinin and some types of chitosan culture media and scaffold, in various arthroscopy products.10 Allograft and xenograft mesh products have also been cited as problematic for patients with issues related to the use of ADIs.11 Authors encourage surgeons to know the source of the products they use as well as the basic requirements of their patient’s faith, possibly even gaining informed consent before the use of animal-derived surgical implants.8,11

CURRENT AMA POLICY

No AMA policy addresses this issue.

CONCLUSION

Several medication ingredients, both active and inactive, and surgical products contain ingredients derived from animal sources. Patients may have strong religious convictions and cultural beliefs leading them to object to using medical products with animal-derived ingredients.
It has been documented that physicians may have a hard time determining the origin of ingredients because the information is inconsistently reported, difficult to obtain, and sometimes incorrect. Many times, reading the list of ingredients of a medical product will not clarify if the product contains any animal-derived ingredients or components. Additionally, the products can vary in regard to ADIs based on the manufacturer, and between brand name and generic versions.

Because no requirement exists for a manufacturer to declare how an ingredient is sourced on label information, this information is not present in clinical decision support systems for physicians and drug databases. Including additional information, such as the presence of ADIs and their source, in the ingredients lists on drug labels and in product information would be beneficial because this information could then be included in information systems used by clinicians and would be more accessible to patients.

RECOMMENDATION

The Board of Trustees recommends the following be adopted in lieu of Resolution 515-A-18, and the remainder of the report be filed:

Animal-Derived Ingredients

Our AMA:

1. Urges the U.S. Food and Drug Administration to require manufacturers to include all ingredients and components present in medical products on the product label, including both active and inactive ingredients, and denote any derived from an animal source. (New HOD Policy)

2. Encourages cultural awareness regarding patient preferences associated with medical products containing active or inactive ingredients or components derived from animal sources. (New HOD Policy)

Fiscal Note: Less than $500
REFERENCES

4. 21 U.S.C. ch. 9 § 301.
7. 21 C.F.R. pt. 201
Whereas, Current AMA policy calls for physicians to “report the results of research accurately, including subsequent negative findings”, particularly when “the findings do not support the research hypothesis”;¹ and

Whereas, There are hurdles to the publication of negative research findings because of publication bias wherein journals are less likely to accept manuscripts reporting negative findings;² and

Whereas, The AMA supports the reproducibility of research findings by advocating that scientific research “employ study designs that will yield scientifically valid and significant data”;³ and

Whereas, There is a systemic lack of reproducibility among published biomedical research studies⁴, as highlighted by a recent report finding that nearly 70% of researchers were unable to reproduce another scientist’s results;⁴,⁵ and

Whereas, Preregistration of a research study is the act of committing to clearly defined research questions and analytical plans prior to the observation of the research outcomes, usually achieved by posting an analysis plan to an independent registry;⁶ and

Whereas, Establishing hypotheses prior to observation of outcomes has been associated with a four-fold reduction in rates of reporting false positive findings, suggesting that preregistration can increase replicability of research;⁷ and

Whereas, The proportion of large clinical trials reporting negative findings increased from 43% to 92% after preregistration of clinical trials became mandatory in the United States, showing that “preregistration is correlated with outcomes that suggest reduced publication or reporting biases”;⁸ therefore be it

¹ AMA Code of Medical Ethics Opinion E-7.2.1 Principles for Disseminating Research Results
³ AMA Code of Medical Ethics Opinion E-7.1.3 Study Design and Sampling
RESOLVED, That our American Medical Association support preregistration in order to mitigate publication bias and improve the reproducibility of biomedical research. (New HOD Policy)

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

Date Received: 09/21/18

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
Issued: 2016

E-7.2.1 Principles for Disseminating Research Results
Physicians have an ethical responsibility to learn from and contribute to the total store of scientific knowledge. When they engage in biomedical or health research, physicians have obligations as scientists, which include disseminating research findings. Prompt presentation to scientific peers and publication of research findings are foundational to good medical care and promote enhanced patient care, early evaluation of clinical innovations, and rapid dissemination of improved techniques.

To fulfill their ethical responsibilities with respect to sharing research findings for the ultimate benefit of patients, physicians should:
(a) Advocate for timely and transparent dissemination of research data and findings. Physicians should not intentionally withhold information for reasons of personal gain.
(b) Report the results of research accurately, including subsequent negative findings. This is particularly important where the findings do not support the research hypothesis.
(c) Maintain a commitment to peer review.
(d) Disclose sponsorship and conflicts of interest relating to the research, in keeping with ethics guidance.
(e) Be responsible in their release of research results to the media, ensuring that any information the researcher provides is prompt and accurate and that informed consent to the release of information has
been obtained from research participants (or participants legally authorized representative when the participant lacks decision-making capacity) prior to releasing any identifiable information. In rare circumstances, the potential for misuse of research results could affect the decision about when and whether to disseminate research findings. Physician-researchers should assess foreseeable ramifications of their research in an effort to balance the promise of benefit against potential harms from corrupt application. Only under rare circumstances should findings be withheld, and then only to the extent required to reasonably protect against misuse. 

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

Issued: 2016

Food Additives H-150.998

Our AMA supports the passage of legislation that would amend the Food Additive Act to require evidence based upon scientifically reproducible studies of the association of food additives with an increased incidence of cancer in animals or humans at dosage levels related to the amounts calculated as normal daily consumption for humans before removal of an additive from the market.

Citation: (Sub. Res. 4, A-77; Reaffirmed: CLRPD Rep. C, A-89; Reaffirmed: Sunset Report, A-00; Modified: BOT Rep. 6, A-10)

Increasing Minority Participation in Clinical Research H-460.911

1. Our AMA advocates that:
   a. The Food and Drug Administration (FDA) conduct annual surveillance of clinical trials by gender, race, and ethnicity, including consideration of pediatric and elderly populations, to determine if proportionate representation of women and minorities is maintained in terms of enrollment and retention. This surveillance effort should be modeled after National Institute of Health guidelines on the inclusion of women and minority populations.
   b. The FDA have a page on its web site that details the prevalence of minorities and women in its clinical trials and its efforts to increase their enrollment and participation in this research; and
   c. Resources be provided to community level agencies that work with those minorities who are not proportionately represented in clinical trials to address issues of lack of access, distrust, and lack of patient awareness of the benefits of trials in their health care. These minorities include Hispanics, Asians/Pacific Islanders/Native Hawaiians, and Native Americans.

2. Our AMA recommends the following activities to the FDA in order to ensure proportionate representation of minorities in clinical trials:
   a. Increased fiscal support for community outreach programs; e.g., culturally relevant community education, community leaders’ support, and listening to community’s needs;
   b. Increased outreach to female physicians to encourage recruitment of female patients in clinical trials;
   c. Continued minority physician education on clinical trials, subject recruitment, subject safety, and possible expense reimbursements;
   d. Support for the involvement of minority physicians in the development of partnerships between minority communities and research institutions; and
   e. Fiscal support for minority recruitment efforts and increasing trial accessibility through transportation, child care, reimbursements, and location.

3. Our AMA advocates that specific results of outcomes in all clinical trials, both pre- and post-FDA approval, are to be determined for all subgroups of gender, race and ethnicity, including consideration of pediatric and elderly populations; and that these results are included in publication and/or freely distributed, whether or not subgroup differences exist.

Whereas, One in 6 women and 1 in 33 men have experienced an attempted or completed rape in their lifetime, and there were 323,450 reports of rape or sexual assault in the United States in 2016;1,2 and

Whereas, Hospital emergency departments (EDs) typically serve as the primary point of care for survivors of sexual assault, accounting for approximately 65,000–90,000 emergency department visits per year;3 and

Whereas, The medical forensic examination (MFE) consists of a full head-to-toe physical examination focused on documenting a patient’s physical injuries and procuring DNA evidence to assist in the prosecution of a case;4 and

Whereas, Performing a MFE has been shown to increase prosecution rates, and patients who have chosen to undergo the MFE may do so to gain closure and emotional healing from the traumatic event;5 and

Whereas, While the MFE can be completed by a variety of healthcare providers including emergency medicine (EM) physicians, nurses/nurse practitioners, and physician assistants, EM physicians are the primary examiner performing these exams despite recommendations that encourage the involvement of other providers;4,6 and

Whereas, The MFE takes on average two hours to perform, must be completed within 72 hours of the assault, and a chain of custody must be maintained where the examiner cannot leave the evidence unattended until it is sealed for storage or handed to an authorized law enforcement agent;4,7 and

Whereas, EM physicians typically see 2.48 patients per hour, which makes it difficult to effectively complete the MFE and maintain custody of the evidence alongside their clinical responsibilities;4,8 and

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Whereas, There is currently no national consensus on EM resident education for sexual assault examinations, leading to EM physicians who are undertaught to complete the MFE;¹⁹ and

Whereas, Sexual assault nurse examiners (SANE) are health care personnel specially trained to perform the MFE and their involvement is associated with higher rates of survivors' psychological recovery and offender prosecution due to better collection of forensic data;¹⁰,¹¹ and

Whereas, Although there are now over 600 SANE programs nationwide, many EDs lack access to SANE personnel, especially in rural or smaller communities;¹²,¹³ and

Whereas, The United States Government Accountability Office released a study highlighting "weak stakeholder support for examiners" as one of the main reasons for poor availability of SANE personnel;¹⁴ and

Whereas, The American College of Emergency Physicians, the International Association of Forensic Nurses, and the Department of Justice all recommend that the MFE be performed by specially trained medical personnel such as a SANE, and the Police Foundation in Texas found that there is "reluctance by nurses, hospital administrators and criminal justice officials to [have] non-SANEs conduct medical forensic exams";¹⁴,¹⁵ and

Whereas, Expanding the SANE program nationwide may decrease the burden on ED physicians and provide better care to sexual assault survivors;⁴,¹⁵, therefore be it

RESOLVED, That our American Medical Association advocate for increased patient access to sexual assault nurse examiners in the emergency department. (New HOD Policy)

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

Date Received: 09/21/18

RELEVANT AMA POLICY

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.


**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

**Access to Emergency Contraception H-75.985**
It is the policy of our AMA: (1) that physicians and other health care professionals should be encouraged to play a more active role in providing education about emergency contraception, including access and informed consent issues, by discussing it as part of routine family planning and contraceptive counseling; (2) to enhance efforts to expand access to emergency contraception, including making emergency contraception pills more readily available through pharmacies, hospitals, clinics, emergency rooms, acute care centers, and physicians' offices; (3) to recognize that information about emergency contraception is part of the comprehensive information to be provided as part of the emergency treatment of sexual assault victims; (4) to support educational programs for physicians and patients regarding treatment options for the emergency treatment of sexual assault victims, including information about emergency contraception; and (5) to encourage writing advance prescriptions for these pills as requested by their patients until the pills are available over-the-counter.

Citation: (CMS Rep. 1, I-00; Appended: Res. 408, A-02; Modified: Res. 443, A-04; Reaffirmed: CSAPH Rep. 1, A-14)

**HIV, Sexual Assault, and Violence H-20.900**
Our AMA believes that HIV testing should be offered to all victims of sexual assault, that these victims should be encouraged to be retested in six months if the initial test is negative, and that strict confidentiality of test results be maintained.

Citation: (CSA Rep. 4, A-03; Modified: CSAPH Rep. 1, A-13)
Whereas, Many front-of-package (FOP) labels on food products feature nutrient claims that suggest or imply that a food has certain nutritional properties related to its content of energy, proteins, fats, carbohydrates, dietary fiber, vitamins, and/or minerals; and

Whereas, FOP labels attract attention, thereby causing consumers to spend less time reading the nutrition facts on the back and side panel of food products\(^1\); and

Whereas, Research demonstrates that consumers will exhibit a preference for a product with a FOP nutrient claim regardless of its qualitative value\(^3\); and

Whereas, Studies show that children perceive food products with nutrient claims on their FOP label as healthier\(^4\); and

Whereas, Studies of responses to nutrition-related claims in food advertising have found that consumers over-generalize a product’s healthfulness based on narrower claims\(^5,6,7,8\); and

Whereas, Many front-of-package labels (e.g. “Whole Grain” on sugary cereals and “Good Source of Vitamins and Minerals” on toaster pastries) are placed on products that contain high amounts of added sugar,\(^9\) meaning they do not comply with the 2015-2020 U.S. Dietary Guidelines’ recommendation that food products contain no more than 10% added sugars by calorie value; and


Whereas, Evidence shows that individuals who consume diets high in refined carbohydrates are at a greater risk of becoming obese\textsuperscript{10}, developing diabetes\textsuperscript{11}, and dying from a cardiovascular event\textsuperscript{12}; and

Whereas, The Food and Drug Administration (FDA) regulates front-of-package claims by enforcing qualifying criteria that food products must meet for use of each individual nutrient claim\textsuperscript{13}; and

Whereas, The FDA has no requirement that food products labeled with nutrient claims that can be generalized to imply healthfulness adhere to specific macronutrient limits; and

Whereas, Studies show that negative cues in the form of warning labels are demonstrated to have a greater impact on consumer food choices than positive health claims\textsuperscript{14,15,16}; and

Whereas, Standardized warning labels have been mandated in Chile on food products high in sugar, salt, fat, and calories since 2016\textsuperscript{17}; and

Whereas, To avoid having to add warning labels to their products, food companies in Chile have reformulated over 1,500 food products to be lower in sugar, salt, fat, and calories\textsuperscript{18}; and

Whereas, Chilean consumers purchase more of the foods without warning labels than they did before implementation of the warning labels\textsuperscript{19,20}; and

Whereas, Our AMA and AMA-MSS have established support for consumer-level interventions and education about the effects of excessive dietary sugars (H-150.960, H-150.974, H-150.935, H-150.945, D-150.975, D-150.987); and

Whereas, Our AMA and AMA-MSS have established support for the use of warning labels and plain packaging on sugar-sweetened beverages (H-150.927); therefore be it


\textsuperscript{13} Subpart D—Specific Requirements for Nutrient Content Claims, 58 FR 2413 (1993); 58 FR 17343 (1993), as amended at 58 FR § 44033 (1993); 62 FR § 40598 (1997); 63 FR § 40024 (1998); 67 FR § 9585 (2002); 69 FR § 16481 (2004).


\textsuperscript{17} Carreño, I. (2015). Chiles Black STOP Sign for Foods High in Fat, Salt or Sugar. European Journal of Risk Regulation, 6(04), 622-626. doi:10.1017/s1867299x0000516x


RESOLVED, That our American Medical Association support additional U.S. Food and Drug Administration criteria that limit the amount of added sugar a food product can contain if it carries any front-of-package label advertising nutritional or health benefits (New HOD Policy); and be it further

RESOLVED, That our AMA support the use of front-of-package warning labels on foods that contain excess added sugar. (New HOD Policy)

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

Date Received: 09/24/18

RELEVANT AMA POLICY

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

Our AMA:
1. supports federal, state, and local policies to require fast-food and other chain restaurants with 10 or more units (smaller, neighborhood restaurants could be exempt) to provide consumers with nutrition information on menus and menu boards;
2. recommends that nutrition information in fast-food and other chain restaurants include calorie, fat, saturated fat and trans fat, and sodium labeling on printed menus, and, at a minimum, calories on menu boards, since they have limited space, and that all nutrition information be conspicuous and easily legible;
3. urges federal, state, and local health agencies, health organizations, and physicians and other health professionals to educate people how to use the nutrition information provided in restaurants to make healthier food choices for themselves and their families; and
4. urges restaurants to improve the nutritional quality of their menu offerings--for example, by reducing caloric content; offering smaller portions; offering more fruits, vegetables, and whole-grain items; using less sodium; using cooking fats lower in saturated and trans fats; and using less added sugars/sweeteners.

Citation: (Res. 419, A-07; Reaffirmed in lieu of Res. 413, A-09, Res. 416, A-09 and Res. 418, A-09)

Encouraging Healthy Eating Behaviors in Children Through Corporate Responsibility H-150.935

Our AMA: 1) supports and encourages corporate social responsibility in the use of marketing incentives that promote healthy childhood behaviors, including the consumption of healthy food in accordance with federal guidelines and recommendations; and 2) encourages fast food restaurants to establish competitive pricing between less healthy and more healthy food choices in children's meals.

Citation: (Sub. Res. 402, A-11; Reaffirmation A-12; Reaffirmed in lieu of Res. 435, A-12)

Support for Uniform, Evidence-Based Nutritional Rating System H-150.936

1. Our AMA supports the adoption and implementation of a uniform, nutritional food rating system in the US that meets, at a minimum, the following criteria: is evidence-based; has been developed without conflict of interest or food industry influence and with the primary goal being the advancement of public health; is capable of being comprehensive in scope, and potentially applicable to nearly all foods; allows for relative comparisons of many different foods; demonstrates the potential to positively influence consumers' purchasing habits; provides a rating scale that is simple, highly visible, and easy-to-understand and used by consumers at point of purchase; and is adaptable to aid in overall nutritional decision making.
2. Our AMA will advocate to the federal government - including responding to the Food and Drug Administration call for comments on use of front-of-package nutrition labeling and on shelf tags in retail stores - and in other national forums for the adoption of a uniform, evidence-based nutrition rating system that meets the above-referenced criteria.

Citation: (Res. 424, A-10)

Support for Nutrition Label Revision and FDA Review of Added Sugars D-150.974

1. Our AMA will issue a statement of support for the newly proposed nutrition labeling by the Food and Drug Administration (FDA) during the public comment period.
2. Our AMA will recommend that the FDA further establish a recommended daily value (%DV) for the new added
sugars listing on the revised nutrition labels based on previous recommendations from the WHO and AHA).

3. Our AMA will encourage further research into studies of sugars as addictive through epidemiological, observational, and clinical studies in humans.

Citation: (Res. 422, A-14)

**Increasing Awareness of Nutrition Information and Ingredient Lists H-150.948**

Our AMA supports federal legislation or rules requiring restaurants, retail food establishments, and vending machine operators that have menu items common to multiple locations, as well as all school and workplace cafeterias, especially those located in health care facilities, to have available for public viewing ingredient lists, nutritional information, and standard nutrition labels for all menu items.

Citation: (Sub. Res. 411, A-04; Reaffirmation A-07; Reaffirmed in lieu of Res. 413, A-09, Res. 416, A-09 and Res. 418, A-09; Modified: BOT Rep. 1, A-14)

**Strategies to Reduce the Consumption of Beverages with Added Sweeteners H-150.927**

Our AMA: (1) acknowledges the adverse health impacts of sugar-sweetened beverage (SSB) consumption, and support evidence-based strategies to reduce the consumption of SSBs, including but not limited to, excise taxes on SSBs, removing options to purchase SSBs in primary and secondary schools, the use of warning labels to inform consumers about the health consequences of SSB consumption, and the use of plain packaging; (2) encourages continued research into strategies that may be effective in limiting SSB consumption, such as controlling portion sizes; limiting options to purchase or access SSBs in early childcare settings, workplaces, and public venues; restrictions on marketing SSBs to children; and changes to the agricultural subsidies system; (3) encourages hospitals and medical facilities to offer healthier beverages, such as water, unflavored milk, coffee, and unsweetened tea, for purchase in place of SSBs and apply calorie counts for beverages in vending machines to be visible next to the price; and (4) encourages physicians to (a) counsel their patients about the health consequences of SSB consumption and replacing SSBs with healthier beverage choices, as recommended by professional society clinical guidelines; and (b) work with local school districts to promote healthy beverage choices for students.

Citation: CSAPH Rep. 03, A-17;

**Promotion of Healthy Lifestyles I: Reducing the Population Burden of Cardiovascular Disease by Reducing Sodium Intake H-150.929**

Our AMA will:

(1) Call for a step-wise, minimum 50% reduction in sodium in processed foods, fast food products, and restaurant meals to be achieved over the next decade. Food manufacturers and restaurants should review their product lines and reduce sodium levels to the greatest extent possible (without increasing levels of other unhealthy ingredients). Gradual but steady reductions over several years may be the most effective way to minimize sodium levels.

(2) To assist in achieving the Healthy People 2010 goal for sodium consumption, will work with the FDA, the National Heart Lung Blood Institute, the Centers for Disease Control and Prevention, the American Heart Association, and other interested partners to educate consumers about the benefits of long-term, moderate reductions in sodium intake.

(3) Recommend that the FDA consider all options to promote reductions in the sodium content of processed foods.

Citation: CSAPH Rep. 01, A-16

**Obesity as a Major Health Concern H-440.902**

The AMA: (1) recognizes obesity in children and adults as a major public health problem; (2) will study the medical, psychological and socioeconomic issues associated with obesity, including reimbursement for evaluation and management of patients with obesity; (3) will work with other professional medical organizations, and other public and private organizations to develop evidence-based recommendations regarding education, prevention, and treatment of obesity; (4) recognizes that racial and ethnic disparities exist in the prevalence of obesity and diet-related diseases such as coronary heart disease, cancer, stroke, and diabetes and recommends that physicians use culturally responsive care to improve the treatment and management of obesity and diet-related diseases in minority populations; and (5) supports the use of cultural and socioeconomic considerations in all nutritional and dietary research and guidelines in order to treat patients affected by obesity.

Citation: Res. 423, A-98; Reaffirmed and Appended: BOT Rep. 6, A-04; Reaffirmation A-10; Reaffirmed in lieu of Res. 434, A-12; Reaffirmation A-13; Modified: Res. 402, A-17
Whereas, The current 9-1-1 system is primarily built upon an infrastructure that does not uniformly support modern communications technologies including texting, geolocation, and images;¹ ² and

Whereas, Current 9-1-1 infrastructure has continuously been shown to be vulnerable to preventable outages and cyberattacks, which have already temporarily left thousands without access to emergency services;³ ⁴ ⁵ and

Whereas, The Federal Communications Commission (FCC) has already recommended that Congress increase federal incentives to boost state and local 9-1-1 modernization efforts;⁶ and

Whereas, Internet protocol (IP)- based communication technologies allow the transmission of data over the internet, allowing for increased information (such as text and geolocation) to be obtained by the receiver compared to old circuit-switch communication;⁷ and

Whereas, Congress has failed to nationally incorporate IP based technology into existing 9-1-1 infrastructure, which may lead to inaccurate caller location accuracy on calls over wireline in multiple situations;⁸ and

Whereas, 95% of Americans own at least one cellphone, 77% own at least one smartphone, and over 70% of all 9-1-1 calls are made from cellphones and other handheld devices;⁹ ¹⁰ and

Whereas, While the IP-based geolocation accuracy of handheld devices averages about 4.9 meters, current U.S. standards merely mandate that 67% of 9-1-1 calls are accurate within range of 50 meters, a standard that has not been updated since 2012;¹¹ ¹² and

² Next Generation 9-1-1 Advancement Act of 2011, 47 U.S.C §158. (2012)
¹¹ 911 service, 47 C.F.R. § 20.18(h) (2012).
Whereas, Increased 9-1-1 response times, due to factors such as imprecise call tracking, can lead to increased morbidity in cardiac arrest;\textsuperscript{13} and

Whereas, The Americans with Disabilities Act of 1990 mandates that 9-1-1 services need only receive message-based communication from teletypewriters (TTYs), devices which are distinct and may be incompatible with modern mobile and smartphones;\textsuperscript{14, 15} and

Whereas, Approximately 50 million Americans have hearing disabilities, and 7.5 million Americans have difficulty vocalizing words;\textsuperscript{16, 17} and

Whereas, The FCC found a majority of those with hearing and speech disabilities have discarded their TTYs in favor of mobile plans with SMS services, leaving millions with these disabilities at risk of not being able to effectively communicate with 9-1-1 operators;\textsuperscript{15} and

Whereas, Nationally, 9-1-1 call centers are not mandated to accept SMS messages (text-to-911), meaning that a citizen’s locale may dictate the amount of emergency services they have access to;\textsuperscript{18} and

Whereas, The National Association of the Deaf (NAD) and the Hearing Loss Association of America (HLAA) both acknowledge that the existing 9-1-1 infrastructure limits the ability of those with deafness or hearing loss to contact emergency services;\textsuperscript{19, 20} and

Whereas, The NAD and HLAA both support continued modernization of 9-1-1 services, including the continued implementation of text-to-911;\textsuperscript{19, 20} and

Whereas, Our AMA has adopted policy encouraging guidelines that protect against the reallocation of 9-1-1 funding to unrelated programs (H-440.822), but does not currently encourage the continued modernization of 9-1-1 services; therefore be it

RESOLVED, That our American Medical Association support the funding of federal grant programs for the modernization of the 9-1-1 infrastructure, including incorporation of text to 911 technology. (New HOD Policy)

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

Date Received: 09/24/18

RELEVANT AMA POLICY

Accountability of 911 Emergency Services Funding H-440.822

Our AMA encourages federal guidelines and state legislation that protects against reallocation of 911 funding to unrelated services.

Citation: Res. 220, A-17


AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 905
(I-18)

Introduced by: Medical Student Section

Subject: Support Offering HIV Post Exposure Prophylaxis to All Survivors of Sexual Assault

Referred to: Reference Committee K
(Darlyne Menscer, MD, Chair)

Whereas, 19.3% of women and 1.7% of men in the United States report being raped during their lifetime, and 1.8 per 1000 children have been sexually abused;¹ and

Whereas, The Centers for Disease Control and Prevention (CDC) estimates the risk of contracting HIV from a known HIV-positive person through consensual vaginal intercourse at 0.1%–0.2% and anal intercourse at 0.5%–3%, and this risk may increase during sexual assault due to injuries sustained by the individual;²,³ and

Whereas, Post-Exposure Prophylaxis (PEP) is antiretroviral medication (ART) taken within 72 hours of HIV exposure to prevent infection, and is extremely effective at preventing seroconversion after HIV exposure;⁴,⁵,⁶,⁷,⁸,⁹,¹⁰ and

Whereas, Current CDC guidelines indicate that persons with nonoccupational exposure to HIV should be offered PEP within 72 hours even if the HIV status of the exposer is unknown;¹¹,¹² and

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Whereas, Hospital emergency departments (EDs) typically serve as the primary point of care for survivors of sexual assault, accounting for approximately 65,000–90,000 emergency department visits per year;¹³ and

Whereas, Only 14.5% of assault survivors were offered PEP, and only 8.5% of uninsured assault survivors were offered PEP in a 2009 survey of 117 Los Angeles Emergency Departments;¹⁴ and

Whereas, A 2018 meta-analysis found that the nationally pooled mean of individuals who were sexually assaulted and offered PEP at studied emergency departments was 55.9%;¹⁵ and

Whereas, There is no national consensus on emergency medicine residents' education about sexual assault examinations, which results in suboptimal care for the survivors of sexual assaults;¹³,¹⁶,¹⁷,¹⁸,¹⁹ and

Whereas, A qualitative study in 2016 of sexual assault patients found that physicians neglecting to offer PEP is a major barrier to patient access, disproportionately affecting those who are homeless or uninsured;¹¹,²⁰ and

Whereas, The same study indicated that the physicians neglected to offer PEP or they provided incorrect counseling due to a lack of knowledge about state or national PEP guidelines and a 2013 study found 20% of emergency physicians were not aware CDC PEP guidelines;²⁰,²¹ and

Whereas, The cost of PEP is between $600-$1000, and persons prescribed PEP after sexual assault can be reimbursed for medications and clinical care costs through state Crime Victim’s Compensation Programs funded by the U.S. Department of Justice;²²,²³,²⁴ and

¹⁸ Monika K Goyal et al., “Enhancing the Emergency Department Approach to Pediatric Sexual Assault Care: Implementation of a Pediatric Sexual Assault Response Team Program.,” Pediatric Emergency Care 29, no. 9 (September 2013): 969–73, doi:10.1097/PEC.0b013e3182a21a0d.
Whereas, The estimated lifetime cost for HIV treatment was $367,134 in 2009 and $379,668 in 2010, and the estimated medical cost saved by preventing one HIV infection is $229,800;\textsuperscript{25,26}

and

Whereas, Many living with HIV may find it challenging to perform daily tasks, participate in moderate physical activities, or have the energy to engage in an active social life;\textsuperscript{27} therefore be it

RESOLVED, That our American Medical Association advocate for education of physicians about the effective use of HIV Post-Exposure Prophylaxis (PEP) and the U.S. PEP Clinical Practice Guidelines (New HOD Policy); and be it further

RESOLVED, That our AMA support increased public education about the effective use of Post-Exposure Prophylaxis for HIV (New HOD Policy); and be it further

RESOLVED, That our AMA amend policy H-20.900 by addition and deletion as follows:

\textbf{H-20.900, “HIV, Sexual Assault, and Violence”}

Our AMA believes that HIV testing and Post-Exposure Prophylaxis (PEP) should be offered to all victims survivors of sexual assault, that these victims survivors should be encouraged to be retested in six months if the initial test is negative, and that strict confidentiality of test results be maintained. (Modify Current HOD Policy)

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

Date Received: 09/21/18

\textbf{RELEVANT AMA POLICY:}

\textbf{E-8.1 Routine Universal Screening for HIV}

Physicians primary ethical obligation is to their individual patients. However, physicians also have a long-recognized responsibility to participate in activities to protect and promote the health of the public. Routine universal screening of adult patients for HIV helps promote the welfare of individual patients, avoid injury to third parties, and protect public health.

Medical and social advances have enhanced the benefits of knowing ones HIV status and at the same time have minimized the need for specific written informed consent prior to HIV testing. Nonetheless, the ethical tenets of respect for autonomy and informed consent require that physicians continue to seek patients informed consent, including informed refusal of HIV testing.

To protect the welfare and interests of individual patients and fulfill their public health obligations in the context of HIV, physicians should:

(a) Support routine, universal screening of adult patients for HIV with opt-out provisions.

(b) Make efforts to persuade reluctant patients to be screened, including explaining potential benefits to the patient and to the patients close contacts.

(c) Continue to uphold respect for autonomy by respecting a patients informed decision to opt out.

(d) Test patients without prior consent only in limited cases in which the harms to individual autonomy are offset by significant benefits to known third parties, such as testing to protect occupationally exposed health care professionals or patients.

(e) Work to ensure that patients who are identified as HIV positive receive appropriate follow-up care and counseling.

(f) Attempt to persuade that patients who are identified as HIV positive to cease endangering others.


\textsuperscript{26} Bruce R Schackman et al., “The Lifetime Medical Cost Savings from Preventing HIV in the United States.,” Medical Care 53, no. 4 (April 2015): 293–301, doi:10.1097/MLR.0000000000000308.

(g) Be aware of and adhere to state and local guidelines regarding public health reporting and disclosure of HIV status when a patient who is identified as HIV positive poses significant risk of infecting an identifiable third party. The doctor may, if permitted, notify the endangered third party without revealing the identity of the source person. 

(h) Safeguard the confidentiality of patient information to the greatest extent possible when required to report HIV status. 

AMA Principles of Medical Ethics: I, VI, VII 
Issued: 2016

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

HIV, Sexual Assault, and Violence H-20.900 
Our AMA believes that HIV testing should be offered to all victims of sexual assault, that these victims should be encouraged to be retested in six months if the initial test is negative, and that strict confidentiality of test results be maintained. 
Citation: (CSA Rep. 4, A-03; Modified: CSAPH Rep. 1, A-13)

Access to Emergency Contraception H-75.985 
It is the policy of our AMA: (1) that physicians and other health care professionals should be encouraged to play a more active role in providing education about emergency contraception, including access and informed consent issues, by discussing it as part of routine family planning and contraceptive counseling; (2) to enhance efforts to expand access to emergency contraception, including making emergency contraception pills more readily available through pharmacies, hospitals, clinics, emergency rooms, acute care centers, and physicians' offices; (3) to recognize that information about emergency contraception is part of the comprehensive information to be provided as part of the emergency treatment of sexual assault victims; (4) to support educational programs for physicians and patients regarding treatment options for the emergency treatment of sexual assault victims, including information about emergency contraception; and (5) to encourage writing advance prescriptions for these pills as requested by their patients until the pills are available over-the-counter. 
Citation: (CMS Rep. 1, I-00; Appended: Res. 408, A-02; Modified: Res. 443, A-04; Reaffirmed: CSAPH Rep. 1, A-14)

HIV Postexposure Prophylaxis for Medical Students During Electives Abroad D-295.970 
Our AMA: (1) recommends that US medical schools ensure that medical students who engage in clinical rotations abroad have immediate access to HIV prophylaxis; and (2) encourages medical schools to provide information to medical students regarding the potential health risks of completing a medical rotation abroad, and on the appropriate precautions to take to minimize such risks. 
Citation: (Res. 303, A-02; Reaffirmed: CCB/CLRPD Rep. 4, A-12)

Pre-Exposure Prophylaxis (PrEP) for HIV H-20.895 
1. Our AMA will educate physicians and the public about the effective use of pre-exposure prophylaxis for HIV and the US PrEP Clinical Practice Guidelines. 
2. Our AMA supports the coverage of PrEP in all clinically appropriate circumstances. 
3. Our AMA supports the removal of insurance barriers for PrEP such as prior authorization, mandatory consultation with an infectious disease specialist and other barriers that are not clinically relevant. 
4. Our AMA advocates that individuals not be denied any insurance on the basis of PrEP use. 
Citation: Res. 106, A-16; Modified: Res. 916, I-16; Appended: Res. 101, A-17
Whereas, More than 3.5 million Americans will experience homelessness at some point in a
given year, and 77,486 of these individuals are chronically homeless;¹,² and

Whereas, The AMA supports public policy initiatives pertaining to access to care, and in
particular supports improving health outcomes and decreasing health care costs for the
homeless population (H-160.903, H-160.798, H-345.975, H-185.944); and

Whereas, Lack of identification serves as a major barrier for homeless individuals seeking
medical care, in particular preventing them from enrolling in Medicaid, with 45.1% of the
homeless without photo identification denied access to Medicaid or medical services;³,⁴,⁵ and

Whereas, Over 36% of the U.S. homeless population suffers from a severe mental illness or
chronic substance abuse, and lack of identification among the homeless prevents them from
accessing drug treatment and rehabilitation programs;⁶,⁷ and

Whereas, Forty-three states allow for pharmacists to require photograph identification from
individuals prior to dispensing prescription drugs;⁸ and

Whereas, Unsheltered homeless individuals often have poorer health, less access to
healthcare, and an increased risk of premature mortality compared to the sheltered homeless;⁹

Detroit: 2017 Annual Homeless Assessment Report.<https://static1.squarespace.com/static/5344557fe4b0323896c3c519f/5a7c751608522985c2a3c780/1518105882011/2017+AHAR+
All+Persons+Report+FINAL+from+HDx.pdf>
⁸ National Alliance for Model State Drug Laws. (2018). States that Require ID Prior to Dispensing Controlled Substances or Non-
E158-6B44-A6E69A0729B70C0>
Risk Factors for Mortality: Findings From the 100 000 Homes Campaign. Public Health Reports, 131(6), 765-772.
doi:10.1177/0033354916667501
Whereas, The National Law Center on Homelessness and Poverty found that 54.1% of homeless individuals were denied housing or shelter due to lack of identification; and

Whereas, Recent national surveys have shown that 28% of homeless individuals do not get enough to eat, with 40% report going one or more days without food due to the inability to afford it; and

Whereas, Lack of identification can prevent homeless individuals who qualify for Supplemental Nutrition Assistance Program (SNAP) benefits from accessing this service, as the application process requires personal identification; as a result, only 37% of the homeless population receives SNAP benefits; and

Whereas, Lack of identification causes homeless individuals to delay care due to lack of insurance, and therefore has a systemic economic impact through increased emergency department utilization and presentation in more advanced disease stages; and

Whereas, The Medicaid application process includes verifying the applicant’s Social Security Number, yet a replacement Social Security card requires a form of identification such as driver’s license, state-issued non-driver identification card, or U.S. passport; and

Whereas, The average application fees to obtain a birth certificate and passport in the U.S. are $15.81 and $97, respectively; and

Whereas, A national study found that 36% of homeless individuals could not obtain a photo identification because they could not afford it; and

Whereas, The state of California passed a law allowing homeless individuals to obtain free photo identification, and a number of other state legislatures are in the process of doing the same; therefore be it

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RESOLVED, That our American Medical Association recognize that among the homeless population, lack of identification serves as a barrier to accessing medical care and fundamental services that support health (New HOD Policy); and be it further

RESOLVED, That our AMA support legislative and policy changes that streamline, simplify, and reduce or eliminate the cost of obtaining identification cards for the homeless population. (New HOD Policy)

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

Date Received: 09/21/18

RELEVANT AMA POLICY

The Mentally Ill Homeless H-160.978
(1) The AMA believes that public policy initiatives directed to the homeless, including the homeless mentally ill population, should include the following components: (a) access to care (e.g., integrated, comprehensive services that permit flexible, individualized treatment; more humane commitment laws that ensure active inpatient treatment; and revisions in government funding laws to ensure eligibility for homeless persons); (b) clinical concerns (e.g., promoting diagnostic and treatment programs that address common health problems of the homeless population and promoting care that is sensitive to the overriding needs of this population for food, clothing, and residential facilities); (c) program development (e.g., advocating emergency shelters for the homeless; supporting a full range of supervised residential placements; developing specific programs for multiproblem patients, women, children, and adolescents; supporting the development of a clearinghouse; and promoting coalition development); (d) educational needs; (e) housing needs; and (f) research needs. (2) The AMA encourages medical schools and residency training programs to develop model curricula and to incorporate in teaching programs content on health problems of the homeless population, including experiential community-based learning experiences. (3) The AMA urges specialty societies to design interdisciplinary continuing medical education training programs that include the special treatment needs of the homeless population.
Citation: BOT Rep. LL, A-86; Reaffirmed: Sunset Report, I-96; Reaffirmed: CMS Rep. 8, A-06; Reaffirmed: CMS Rep. 01, A-16

Eradicating Homelessness H-160.903
Our American Medical Association: (1) supports improving the health outcomes and decreasing the health care costs of treating the chronically homeless through clinically proven, high quality, and cost effective approaches which recognize the positive impact of stable and affordable housing coupled with social services; (2) recognizes that stable, affordable housing as a first priority, without mandated therapy or services compliance, is effective in improving housing stability and quality of life among individuals who are chronically-homeless; (3) recognizes adaptive strategies based on regional variations, community characteristics and state and local resources are necessary to address this societal problem on a long-term basis; (4) recognizes the need for an effective, evidence-based national plan to eradicate homelessness; and (5) encourages the National Health Care for the Homeless Council to study the funding, implementation, and standardized evaluation of Medical Respite Care for homeless persons.
Citation: Res. 401, A-15; Appended: Res. 416, A-18; Modified: BOT Rep. 11, A-18

Maintaining Mental Health Services by States H-345.975
Our AMA:
1. supports maintaining essential mental health services at the state level, to include maintaining state inpatient and outpatient mental hospitals, community mental health centers, addiction treatment centers, and other state-supported psychiatric services;
2. supports state responsibility to develop programs that rapidly identify and refer individuals with significant mental illness for treatment, to avoid repeated psychiatric hospitalizations and repeated interactions with the law, primarily as a result of untreated mental conditions;
3. supports increased funding for state Mobile Crisis Teams to locate and treat homeless individuals with mental illness;
4. supports enforcement of the Mental Health Parity Act at the federal and state level; and
5. will take these resolves into consideration when developing policy on essential benefit services.
Citation: (Res. 116, A-12; Reaffirmation A-15)

Subscriber Identification Cards H-185.944
Our AMA: (1) urges any pertinent official or governmental agency to require health insurance plans to issue identification cards to its subscribers which prominently identify the full legal name of the insured; name of the policy holder; identification numbers needed for claim submission; and the primary insurance company name with its appropriate mailing address; and (2) will advocate for legislative and regulatory sanctions against insurance companies which present obstacles to the timely filing of claims which result in the denial of benefits.
Citation: (Sub. Res. 716, A-10; Modified: Sub. Res. 715, A-15)
Whereas, As sales of adult incontinence products and baby diapers are projected to increase 48% and 2.6% respectively by 2020, more individuals and families in both populations face similar challenges to accessing necessary incontinence products;¹ and

Whereas, Lack of access to necessary incontinence products leads to prolonged use of soiled diapers, which precipitates health problems including recurrent urinary tract infections, diaper dermatitis, or exacerbation of eczema, leading to an increase in physician’s office and emergency room visits;²,³ and

Whereas, Diaper need, defined as lacking the financial means to purchase an adequate supply of diapers, is a widespread issue affecting parents of all ethnicities and economic statuses, especially those living below the poverty line;⁴ and

Whereas, Among children using diapers, 23% are members of families earning less than 100% of the federal poverty level and an additional 23% live in families earning 100% to 200% of the federal poverty level;¹,⁵ and

Whereas, The national average cost of diapers is $936 annually, the equivalent of 14% of national average annual income;²,⁶ and

Whereas, Diaper need occurs more frequently in parents with mental health needs and contributes to parental stress and depression, factors which in turn have been known to increase the risk of a child’s future behavioral, social, and emotional problems;³,⁴ and

Whereas, Adult incontinence product use is increasing, with the Urology Care Foundation estimating that 25% to 33% of all people in the U.S. suffer from some degree of urinary incontinence, with more than 50% of individuals over 65 having experienced incontinence;⁷,⁸ and

Whereas, Of the 43 million Americans over 65 years of age, 9.4% are living below the federal poverty level;¹ and

Whereas, Seniors can expect to spend approximately $1800 annually on adult diapers, and for low-income individuals this expense “can consume over 10 percent of their annual income”;⁵ and

Whereas, Studies have found that incontinence is detrimental to quality of life through its impact on relationships, self-esteem, employment, travel, and social activities;¹⁰,¹¹,¹² and

Whereas, 18 states have already eliminated sales tax on adult incontinence products and 13 states have eliminated sales tax on diapers by classifying them as medical supplies or clothing, exempting them as medical prescriptions, or having no sales tax at all;²¹ and

Whereas, 32 states still charge sales tax on adult incontinence products and 37 states still charge sales tax on diapers, with the sales tax as high as 7.25 percent;¹³ and

Whereas, Multiple pieces of state and federal legislation have proposed to increase access to adult incontinence products and diapers by removing state taxes, aiding low-income families in purchasing necessary products, and increasing insurance coverage through Medicare and Medicaid; however none have currently passed;¹⁴,¹⁵,¹⁶,¹⁷,¹⁸ and

Whereas, Our AMA already supports the removal of all sales tax on feminine hygiene products in order to increase access to necessary medical products, especially for those who live below the federal poverty line (H-270.953); therefore be it

RESOLVED, That our American Medical Association support increased access to affordable incontinence products. (New HOD Policy)

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

Received: 09/24/18

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¹ Alameda County Board of Supervisors. Legislative Position Request Form. January 11, 2016.
RELEVANT AMA POLICY:

Tax Exemptions for Feminine Hygiene Products H-270.953
Our AMA supports legislation to remove all sales tax on feminine hygiene products.
Citation: Res. 215, A-16

Insurance Coverage for Complete Maternity Care H-185.997
Our AMA (1) reaffirms its policy of encouraging health insurance coverage for care of the newborn from the moment of birth;
(2) urges the health insurance industry and government to include in their plans, which provide maternity benefits, coverage for normal obstetrical care, and all obstetrical complications including necessary intrauterine evaluation and care of the unborn infant;
(3) urges the health insurance industry to offer such plans on the broadest possible basis;
(4) urges the health insurance industry to make available, on an optional basis, coverage for treatment associated with voluntary control of reproduction;
(5) will advocate for expanding coverage of maternity care to dependent women under the age of 26 on their parents' large group plans; and
(6) will advocate that individual, small and large group health plans provide 60 days of newborn coverage for all newborns born to participants in the plan.

Opposition to Proposed Budget Cuts in WIC and Head Start H-245.979
The AMA opposes reductions in funding for WIC and Head Start and other programs that significantly impact child and infant health and education.
Citation: (Res. 246, I-94; Reaffirmed: BOT Rep. 29, A-04; Reaffirmed: BOT Rep. 19, A-14)

Expanding Enrollment for the State Children's Health Insurance Program (SCHIP) H-290.971
Our AMA continues to support:
a. health insurance coverage of all children as a strategic priority;
b. efforts to expand coverage to uninsured children who are eligible for the State Children's Health Insurance Program (SCHIP) and Medicaid through improved and streamlined enrollment mechanisms;
c. the reauthorization of SCHIP in 2007; and

d. supports the use of enrollment information for participation in the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) and/or the federal school lunch assistance program as documentation for SCHIP eligibility in order to allow families to avoid duplication and the cumbersome process of re-documenting income for child health coverage.
Citation: (Res. 118, A-07; CMS Rep. 1, A-07; Reaffirmation A-14)

Adequate Funding of the WIC Program H-245.989
Our AMA urges the U.S. Congress to investigate recent increases in the cost of infant formula, as well as insure that WIC programs receive adequate funds to provide infant formula and foods for eligible children.
Citation: (Res. 269, A-90; Reaffirmed: Sunset Report, I-00; Reaffirmed: CSAPH Rep. 1, A-10)

Dignity and Self Respect H-25.997
The AMA believes that medical care should be available to all our citizens, regardless of age or ability to pay, and believes ardently in helping those who need help to finance their medical care costs. Furthermore, the AMA believes in preserving dignity and self respect of all individuals at all ages and believes that people should not be set apart or isolated on the basis of age. The AMA believes that the experience, perspective, wisdom and skill of individuals of all ages should be utilized to the fullest.
Citation: AMA President's Address, A-61; Reaffirmed: CLRPD C, A-88; Reaffirmed: Sunset Report, I-98; Reaffirmed: CMS Rep. 4, A-08; Modified: CEJA Rep. 06, A-18
Whereas, Almost a fourth of men and women between the age of 18 and 50 currently have a tattoo; and
Whereas, The Food and Drug Administration regulates cosmetics, which are generally pigments used on the surface of the skin, but does not regulate tattoo and permanent makeup inks which are pigments injected with needles below the skin's surface; and
Whereas, Some risks, such as the spread of infections through the use of unsterilized needles, have long been known; and
Whereas, The long term safety of permanent tattoo inks has not been previously studied; and
Whereas, Research has also shown that some pigment migrates from the tattoo site to the body's lymph nodes; and
Whereas, Many pigments used in tattoo inks are industrial-grade colors suitable for printers' ink or automobile paint; and
Whereas, Azo pigments, the organic pigments making up about 60% of the colorants in tattoo inks are not of health concern while chemically intact, they can degrade with the help of bacteria or ultraviolet light and potentially can turn into cancer-causing primary aromatic amines; and
Whereas, Some surveys show that up to 50% of tattoo owners come to regret getting a tattoo; and
Whereas, Lasers are often used to blast apart pigments, sending problematic degradation products into the body and researchers do not know how the degradation products are distributed in the body or how they get excreted; and
Whereas, A study by the Australian government's National Industrial Chemical's Notification and Assessment Scheme (NICNAS) showed the presence of polycyclic aromatic hydrocarbons (PAHs), a group of chemicals known to be carcinogens in more than one-fifth of 49 inks tested and in 83% of the black inks tested; and
Whereas, Tattoo inks may also contain potentially harmful metal impurities such as chromium, nickel, copper, and cobalt; and
Whereas, Manufacturers of tattoo and permanent makeup inks in the United States are often protected from divulging the ingredients of tattoo inks under the guise of considering them 'trademark secrets'; and
Whereas, In 2008, the Council of Europe, an organization focused on promoting human rights and the integration of regulatory functions in the continent, recommended policies to ensure the safety of tattoos and permanent makeup, which advocate the banning of sixty-two hazardous chemicals, as well as guidelines which include that tattoo and permanent makeup products should contain the following information on the packaging: the name and address of the manufacturer or the person responsible for placing the product on the market, the date of minimum durability, the conditions of use and warnings, the batch number or other reference used by the manufacturer for batch identification, the list of ingredients according to their International Union of Pure and Applied Chemistry (IUPAC) name, CAS Number (chemical Abstract Service of the American Chemical Society) or Colour index (CI) number, and the guarantee of sterility of the contents; and

Whereas, AMA policy H-440.909, “Regulation of Tattoo Artists and Facilities,” currently only encourages the state regulation of tattoo artists and tattoo facilities to ensure adequate procedures to protect the public health, and encourages physicians to report all adverse reactions associated with tattooing to the Food and Drug Administration MedWatch program; and

Whereas, Current regulation of tattoo and permanent makeup inks in the United States performed at state or provincial levels generate a wide variety of guidelines and hygiene standards; therefore be it

RESOLVED, That our American Medical Association encourage the Food and Drug Administration to adopt regulatory standards for tattoo and permanent makeup inks that include at minimum the disclosures expected for injectable drugs and cosmetics and mandate that this information be available to both the body licensed to perform the tattoo and to the person receiving the tattoo (New HOD Policy); and be it further

RESOLVED, That our AMA study the safety of any chemical in tattoo and permanent makeup inks. (Directive to Take Action)

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

Received: 09/27/18

References:
2 https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048919.htm
5 https://search.coe.int/cm/Pages/result_details.aspx?ObjectID=09000016805d3dc4

RELEVANT AMA POLICY

H-440.909 Regulation of Tattoo Artists and Facilities
The AMA encourages the state regulation of tattoo artists and tattoo facilities to ensure adequate procedures to protect the public health; and encourages physicians to report all adverse reactions associated with tattooing to the Food and Drug Administration MedWatch program. (Res. 506, A-96; Reaffirmed: CSAPH Rep. 3, A-06; Reaffirmed: CSAPH Rep. 01, A-16)

H-440.934 Adequacy of Sterilization in Commercial Enterprises
The AMA requests that state health departments ensure the adequacy of sterilization of instruments used in commercial enterprises (tattoo parlors, beauty salons, barbers, manicurists, etc.) because of the danger of exchange of infected blood-contaminated fluids. (Sub. Res. 409, I-92; Reaffirmed: CSA Rep. 8, A-03; Modified: CSAPH Rep. 1, A-13)
Whereas, The Women’s Health and Cancer Rights Act of 1998 (WHCRA) mandates that insurance providers cover reconstructive procedures after mastectomy; and

Whereas, Some insurers have interpreted this language as only covering total mastectomies and not partial mastectomies or lumpectomies and thus deny coverage of reconstructive surgery for patients with deformities after lumpectomies and after radiation; and

Whereas, Breast conservation therapy is often an oncologically safe option for patients, which may leave the breast disfigured; and

Whereas, Radiation therapy in and of itself can lead to pain, fibrosis and deformity of a post-treatment breast; and

Whereas, Technology and techniques for correcting post-lumpectomy and post-radiation deformities have improved and increased, yet insurance interpretation of the WHCRA benefit may limit women’s access to corrective surgery, oncoplastic reconstruction and fat grafting; and

Whereas, Breast reconstruction has been shown to significantly increase physical, social and sexual well-being1; therefore be it

RESOLVED, That our AMA amend Policy H-55.973, “Breast Reconstruction,” by addition and deletion as follows:

Our AMA: (1) believes that reconstruction of the breast for rehabilitation of the postmastectomy cancer post-treatment patient with in situ or invasive breast neoplasm should be considered reconstructive surgery rather than aesthetic surgery; (2) supports education for physicians and breast cancer patients on breast reconstruction and its availability; (3) recommends that third party payers provide coverage and reimbursement for medically necessary breast cancer treatments including but not limited to prophylactic contralateral mastectomy and/or oophorectomy; and (4) recognizes the validity of contralateral breast procedures needed for the achievement of symmetry in size and shape, and urges recognition of these ancillary procedures by Medicare and all other third parties for reimbursement when documentation of medical necessity is provided. (Modify Current HOD Policy)

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

Received: 09/27/18

RELEVANT AMA POLICY

Breast Reconstruction H-55.973
Our AMA: (1) believes that reconstruction of the breast for rehabilitation of the postmastectomy cancer patient should be considered reconstructive surgery rather than aesthetic surgery; (2) supports education for physicians and breast cancer patients on breast reconstruction and its availability; (3) recommends that third party payers provide coverage and reimbursement for medically necessary breast cancer treatments including but not limited to prophylactic contralateral mastectomy and/or oophorectomy; and (4) recognizes the validity of contralateral breast procedures needed for the achievement of symmetry in size and shape, and urges recognition of these ancillary procedures by Medicare and all other third parties for reimbursement when documentation of medical necessity is provided.

CCB/CLRPD Rep. 3, A-14
Whereas, Pornography is now recognized as a factor that directly contributes to and increases all forms of violence against women as well as violence against children; and

Whereas, Exposure to pornography has been demonstrated to increase the likelihood of perpetration of violence, including rape, domestic violence, and sexual harassment; and

Whereas, Literature shows that pornography demonstrably teaches beliefs about women, children, and interpersonal relationships and teaches pathological and/or illegal sexual behaviors (including rape, child molestation, prostitution, domestic violence, pedophilia, sexual harassment, and some paraphilias); and

Whereas, Data demonstrate that pornography normalizes and promotes these pathological and/or illegal behaviors; and

Whereas, Digital access allows average age of first pornography exposure in the early teens during a crucial stage of sexual development in young people; and

Whereas, Pornography can also promote behaviors that increase the risk of sexually transmitted diseases, gastrointestinal fissures/ruptures, post-traumatic stress disorder, sex addiction, and paraphilias; and

Whereas, Four states (Florida, Idaho, Kansas, and Utah) have declared pornography to be a public health risk; therefore be it

RESOLVED, That our American Medical Association support efforts to mitigate the negative public health impacts of pornography as it relates to vulnerable populations, including but not limited to women and children. (New HOD Policy)

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

Received: 09/28/18
References:


RELEVANT AMA POLICY

Child Pornography H-60.990
The AMA (1) encourages and promotes awareness of child pornography issues among physicians; (2) promotes physician awareness of the need for follow-up psychiatric treatment for all victims of child pornography; (3) encourages research on child abuse (including risk factors, psychological and behavioral impact, and treatment efficacy) and dissemination of the findings; and (4) wherever possible, encourages international cooperation among medical societies to be alert to and intervene in child pornography activities.

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

Our AMA:

(1) Recognizes the positive role of the Internet in providing health information to children and youth.

(2) Recognizes the negative role of the Internet in connecting children and youth to predators and exposing them to pornography.

(3) Supports federal legislation that restricts Internet access to pornographic materials in designated public institutions where children and youth may use the Internet.

(4) Encourages physicians to continue efforts to raise parent/guardian awareness about the importance of educating their children about safe Internet and social media use.

(5) Supports school-based media literacy programs that teach effective thinking, learning, and safety skills related to Internet and social media use.

Citation: BOT Rep. 10, I-06; Modified: CSAPH Rep. 01, A-16
Whereas, In the last few decades the United States has achieved remarkable success in reducing the use of tobacco products and the associated negative health consequences; and

Whereas, From a common sense perspective, most would agree that in the case of an individual smoking tobacco vs. e-cigs, the tobacco smoke produces more harmful tars and toxins and individuals have the right to try to switch to e-cigs to reduce inhaling these; and

Whereas, Many physicians believe that because of the addictive - and possible acute inflammatory effects of nicotine on the cardiovascular system - patients be encouraged to try to stop smoking by other means before using e-cigs; and

Whereas, Teens and young adults, up to 21 years of age should avoid all nicotine delivery products because of the risks of addiction and adverse effects on brain development; and

Whereas, The strong divide in the medical and public health communities regarding accessibility of e-cigs, primarily rests on “population” based disagreements and speculations regarding whether they are effective for the complete abstinence from smoking cigarettes, will prove effective over the long term in reducing tobacco use and whether they play a role in addicting youth to nicotine, and possibly tobacco; and

Whereas, Recent debate over the role of inhalation products in further tobacco harm reduction has created confusion within the profession and public, rather than the sage guidance they deserve; and

Whereas, E-cigarettes have been shown to be effective in reducing tobacco use in some adults justifying them as a cessation option, yet, it is also prudent to assure minors are banned from purchasing potentially addictive nicotine substances; and

Whereas, Although abstinence of inhalation of other than prescribed drugs is the healthiest practice, youth continue to experiment with inhalation of substances such as cannabis, corn silk, hookah mixtures and non-drug containing, relatively toxic free, often flavored, “vape” products; therefore be it
RESOLVED, That our American Medical Association advocate for a “protect adult choice and youth’s health” “common sense” tobacco strategy (with a report back to the House of Delegates annually) under which:

- Current educational, promotional and policy initiatives (e.g. taxation) to reduce the use of tobacco products by inhalation and orally would continue, including advocating for the prohibition of the sale of ALL nicotine containing products to individuals under 21 years unless via prescription for medical purposes.

- E-cigarettes (non-tobacco products containing nicotine) would be accessible at an affordable price to adults who wish to use them, and would be available to individuals below 21 years of age only as part of state sanctioned tobacco cessation activities. States and local jurisdictions would be free to require vendors to post warnings regarding the possible health risks of the use of nicotine inhalation products.

- Non-nicotine, non-drug containing vaping and other inhalation products would not be considered tobacco products, but would be monitored by state and local jurisdictions as any other personal use product regarding safety and public accommodation. (New HOD Policy)

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

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