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Subject: Information Regarding Animal-Derived Medications (Resolution 515-A-18)

Presented by: Jack Resneck, Jr., MD, Chair

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

INTRODUCTION

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

1. 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 (ADI) 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. Reports of medication non-adherence or discontinuation because of ADI avoidance exist. 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. Nevertheless, ADI information is inconsistently reported, difficult to obtain, and sometimes incorrect. 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.
- Low molecular weight heparin is porcine-derived.
- Corticotropin is obtained from porcine pituitary gland.
- Hyaluronidase is derived from crude extracts of ovine or bovine testicular tissue.
- Pancreatin (also known as pancreatic enzymes, pancrelipase) is bovine derived.

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. 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.
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
Subject: Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals

Presented by: Robyn F. Chatman, MD, MPH, Chair

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

INTRODUCTION

Policy D-515.980, “Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals,” asks:

That our American Medical Association study recent domestic violence data and the unique issues faced by the LGBTQ population.

METHODS

English language reports were selected from searches of the PubMed and Google Scholar databases from January 2008 to June 2018 using the search terms “gay,” “lesbian,” “bisexual,” “transgender,” “queer,” “LGBT,” and “LGBTQ” in conjunction with the terms “intimate partner violence,” “domestic violence,” and “partner abuse.” Additional articles were identified by manual review of the reference lists of pertinent publications. Websites managed by non-profit and advocacy organizations were also reviewed for relevant information.

CURRENT AMA POLICY

AMA Policy H-160.991, “Health Care Needs of Lesbian, Gay, Bisexual, Transgender and Queer Populations,” recognizes that the physician’s nonjudgmental recognition of patients’ sexual orientation, sexual behaviors, and gender identities enhances their ability to render optimal patient care.” Furthermore, this policy states that our AMA will collaborate with partner organizations to educate physicians on how individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, queer/questioning individuals) experience intimate partner violence (IPV), and how sexual and gender minorities present with IPV differ from their cisgender, heterosexual peers and the fact they may have unique complicating factors. The AMA will also promote crisis resources for LGBTQ patients that cater to the specific needs of LGBTQ survivors of domestic violence (D-515.980, “Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals”). AMA Policy H-515.965, “Family and Intimate Partner Violence,” broadly addresses the physician’s role in IPV and is not specific to patients of a certain gender or sexual orientation. The AMA encourages physicians to routinely inquire about the IPV histories of their patients and upon identifying patients experiencing abuse or threats from intimates, assess and discuss safety issues, and refer patients to appropriate medical or health care professionals and/or community-based trauma-specific resources as soon as possible.
BACKGROUND

IPV describes physical violence, sexual violence, stalking and psychological aggression (including coercive acts) by a current or former intimate partner. Examples of intimate partners include current or former spouses, boyfriends or girlfriends, dating partners, or sexual partners. While IPV can occur between heterosexual or same-sex couples and does not require sexual intimacy, much of the effort to address this public health problem has focused on heterosexual women even though other populations experience IPV at similar rates.

EPIDEMIOLOGY OF IPV IN THE LGBTQ POPULATION

Little is known about the national prevalence of IPV in the LGBTQ population in the United States. While a number of small-scale studies have examined violence in the LGBTQ population, the research is difficult to interpret and generalize due to the variability of methodologies utilized, which include different measures of IPV and different time frames to which the violence corresponds (i.e., past year, lifetime). In addition, researchers have had difficulty recruiting samples that are representative of the LGBTQ population, so the majority of studies have been conducted with small convenience samples. A further complication with the research involves the failure to distinguish between sexual activity (behavior) and sexual identity. These factors have resulted in inconsistent findings in terms of victimization rates among these groups. For example, a systematic review on IPV in self-identified lesbians found that victimization prevalence in studies ranged between 10 to 51 percent.

In 2010, the Centers for Disease Control and Prevention’s (CDC) National Intimate Partner and Sexual Violence Survey (NISVS), provided the first national-level data on the prevalence of intimate partner violence, sexual violence, and stalking among the lesbian, gay, and bisexual (LGB) population by self-reported sexual orientation (transgender individuals were not included in this study). The pattern of results suggests that individuals who self-identify as LGB experience an equal or greater likelihood of experiencing sexual violence, stalking, and intimate partner violence compared with self-identified heterosexuals. The survey found that 61 percent of bisexual women and 44 percent of lesbian women reported experiencing rape, physical violence, and/or stalking within the context of an intimate partner relationship at least once during their lifetime versus 35 percent of heterosexual women. For men, the lifetime prevalence of intimate partner violence was 37 percent for bisexual men, 29 percent for heterosexual men, and 26 percent for gay men.

Limited data is available regarding IPV in transgender and genderqueer people as researchers tend to offer only binary gender identify categories. However, the available evidence suggests these populations are even more vulnerable to LGBTQ-specific IPV tactics. Findings of lifetime IPV among people who are transgender range from 31 percent to 50 percent. One study directly compared the lifetime prevalence of IPV among transgender and cisgender people and found that 31 percent of transgender people and 20 percent of cisgender people had ever experienced IPV or dating violence.

DISCUSSION

Risk Factors

A number of factors can put LGBTQ individuals at increased risk for IPV victimization and perpetration and many of these risk factors are similar to those among heterosexual individuals. Risk factors for IPV victimization include:
racial minority status, lower socioeconomic status, younger age, deaf or hard of hearing, substance use/abuse/dependence, low self-esteem, risky sexual behavior, victim blaming attitudes, lack of power in relationships, attachment anxiety, HIV positive status, child abuse, witnessing IPV as a child, victimization in peer networks, psychological and physical health problems, history of sex work, and history of incarceration.  

Risk factors for IPV perpetration include:
- interpersonal problems, greater conformity to masculine norms, less secure attachments,
- greater psychological distress, more substance use/abuse/dependency, high need for control,
- low socioeconomic status, less education, racial minority status, low self-esteem, more stress, HIV positive status, unprotected sexual intercourse, child abuse, exposure to IPV as a child, disordered personality characteristics, and poor relationship quality.  

**Identity Abuse Tactics**

While some research on the abusive partners’ use of physical and psychological abuse may be generalizable across communities, unique aspects to LGBTQ relationships are believed to exist. This includes identity abuse (IA), which are abuse tactics that leverage systematic oppression to harm an individual. IA tactics of IPV leverage heterosexism and cissexism against LGBTQ survivors. These tactics including threatening to disclose a partner’s LGBTQ status without their consent. This can result in fear of loss of children, employment, housing, or relationships with family and friends. Another IA tactic includes undermining, attacking, or denying a partner’s identity as an LGBTQ person. Examples include accusing a partner of being straight, questioning their authenticity, or being prevented from expressing their gender identity. Other IA tactics include using slurs or derogatory language regarding the partner’s sexual orientation or gender identity and isolating survivors from the LGBTQ community. These tactics are also used in threatening partners who seek help.  

In examining the prevalence of IA in the LGBTQ community, nearly 17 percent of the sample (n=734) of sexual minority adults reported experiencing at least one form of IA in the last year and 40 percent reported experiencing IA at some point in adulthood. In terms of gender, women (43 percent) experienced significantly more exposure to IA in adulthood than men (24 percent). Transgender or gender non-confirming participants (50 percent) reported higher rates of IA in adulthood than their cisgender counterparts. In terms of sexual orientation, queer-identified participants (49 percent) and bisexual participants (48 percent) had the highest rates of IA in adulthood (nearly 50 percent) compared with their lesbian (35 percent) and gay (26 percent) counterparts.  

**Health Outcomes**

IPV is associated with poor physical and mental health outcomes. For example, in a study (n=817) of men who have sex with men there was a significant relationship between a range of health problems and IPV. Abused men were more likely than non-abused men to report problems such as hypertension, heart disease, obesity, smoking-related illness and, to some extent, sexually transmitted infections. Men in abusive relationships were more likely to report depression or other mental health problems, and to engage in unhealthy behaviors such as substance abuse, combining drugs with sex, or unprotected sex. Another study of LGBT young adults (n=172) found that being a victim of IPV was associated with concurrent sexual risk taking and prospective mental health outcomes, but was not associated with substance abuse.
BARRIERS TO SEEKING HELP

Screening

The medical community has been criticized for neglecting members of the LGBTQ population in their efforts to respond to the problem of IPV. However, research is lacking on the best practices for identifying LGBTQ survivors of IPV. It is unclear if existing tools are relevant to LGBTQ survivors, though limited research suggests that they are and that changes in wording and additional questions could improve their relevancy.

U.S. Preventive Services Task Force (USPSTF). The USPSTF recommends that clinicians screen women of childbearing age for IPV, such as domestic violence, and provide or refer women who screen positive to intervention services (B recommendation). In making this recommendation, the USPSTF examined the accuracy of available screening tests, the effectiveness of early detection through trials examining interventions, the potential harms of screening and interventions, and the estimated magnitude of the net benefit. The USPSTF, in discussing clinical considerations, recognized that a significant body of evidence is lacking for other populations, especially men. It was noted that research is needed in all areas related to screening and treatment in men, as well as reporting, safety, community linkages and supports, legal ramifications, and cultural aspects. The USPSTF is in the process of updating this recommendation, but the draft statement that has been posted indicates that research gaps still exist. However, the draft recommendation does not specifically note the gaps in research related to the LGBTQ population.

Futures Without Violence has collaborated with a number of organizations to develop materials that are specifically for LGBTQ people. The “Caring Relationships, Healthy You” safety cards and poster are survivor-centered tools that are useful conversation starters for health care providers who are doing universal education around healthy relationships and assessing for IPV.

Interventions and Services

In addition to effective screening tools, more research is needed to determine the interventions that are effective in reducing the harms of IPV in the LGBTQ population. For women of childbearing age, effective interventions include ongoing support services focused on counseling and home visits, those that address multiple risk factors (not just IPV), or include parenting support for new mothers. However, IPV interventions should be culturally relevant, tailored to specific groups, and evaluated within those groups.

There is limited knowledge about LGBTQ IPV in the general community and limited resources are available to support LGBTQ survivors. When LGBTQ individuals attempt to access IPV services, their options are often severely limited. When services are provided to LGBTQ IPV survivors, the lack of cultural competency and informed support can re-traumatize the victim. Gaps in services include: limited LGBTQ-friendly health care services, lack of adequate training at agencies around LGBTQ issues, limited medical access, and intake forms that are not LGBTQ friendly. A 2010 study by the National Coalition of Anti-Violence Programs surveyed domestic violence agencies, sexual assault centers, prosecutors’ offices, law enforcement agencies, and child victim services (n=648). The survey found that 94 percent of respondents were not serving LGBTQ survivors of IPV. For example, in 2011, more than 60 percent of LGBTQ IPV survivors who sought assistance at a shelter were turned away.

Similar barriers exist in seeking support from law enforcement and the justice system. LGBTQ individuals are hesitant to seek law enforcement assistance and this hesitation is likely due to fear
of discrimination or harassment. Furthermore, state laws may not specifically grant protections to LGBTQ survivors. For example, state statutes on protection orders that do not include LGBTQ survivors are often decided on a case-by-case basis and are at the discretion of a judge.

**LEGISLATION**

*Violence Against Women Reauthorization Act of 2013*

The Violence Against Women Act (VAWA) reauthorization of 2013 attempted to address the lack of services for LGBTQ survivors by including a non-discrimination clause. This clause provided that no person in the United States shall, based on actual or perceived race, color, religion, national origin, sex, gender identity, be excluded from participation in, be denied the benefits of, or be subjected to discrimination under any program or activity funded in whole or in part with funds made available under VAWA and any other program or activity funded in whole or in part with funds appropriated by the Office on Violence Against Women. While there has not been an evaluation on the impact of this clause, it is worth noting that VAWA is up for reauthorization in 2018 and there are concerns this provision may be removed.

**CONCLUSION**

The lifetime prevalence of IPV in the LGBTQ community is estimated to be comparable to or higher than that among heterosexual couples. Much of the work that has been done to address the public health problem of IPV has focused on heterosexual women. There is limited information available on the aspects of IPV that are unique to same-sex relationships and the effects on LGBTQ survivors’ mental and physical health. Research is also lacking on the best practices for identifying LGBTQ survivors of IPV. It is unclear if existing screening tools are relevant to LGBTQ survivors. In addition to effective screening tools, research is needed to determine the interventions that are effective in reducing the harms of IPV in the LGBTQ population. Furthermore, community resources to support LGBTQ survivors of IPV are limited. While the 2013 reauthorization of VAWA specifically provided for non-discrimination against sexual and gender minorities, the implementation and enforcement of this provision is unclear.

Despite the limited research available on this topic, physicians should be alert to the possibility of IPV among their LGBTQ patients and should familiarize themselves with resources available in their communities for LGBTQ survivors of IPV.

**RECOMMENDATIONS**

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

1. **That Policy D-515.980, “Improving Screening and Treatment Guidelines for Domestic Violence Against Lesbian, Gay, Bisexual, Transgender, Queer/Questioning, and Other Individuals” be amended by addition and deletion to read as follows:**

   Our AMA will: (1) study recent domestic violence data and the unique issues faced by the LGBTQ population, and (2) promote crisis resources for LGBTQ patients that cater to the specific needs of LGBTQ victims of domestic violence, (2) encourage physicians to familiarize themselves with resources available in their communities for LGBTQ survivors of intimate partner violence, and (3) advocate for federal funding to support programs and services for survivors of intimate partner violence that do not discriminate against underserved
2. Our AMA encourages research on intimate partner violence in the LGBTQ community to include studies on the prevalence, the accuracy of screening tools, effectiveness of early detection and interventions, as well as the benefits and harms of screening. (New HOD Policy)


Our AMA will collaborate with our partner organizations to educate physicians regarding: (i) the need for sexual and gender minority individuals to undergo regular cancer and sexually transmitted infection screenings based on anatomy due to their comparable or elevated risk for these conditions; and (ii) the need for comprehensive screening for sexually transmitted diseases in men who have sex with men; (iii) appropriate safe sex techniques to avoid the risk for sexually transmitted diseases; and (iv) that individuals who identify as a sexual and/or gender minority (lesbian, gay, bisexual, transgender, queer/questioning individuals) experience intimate partner violence, and how sexual and gender minorities present with intimate partner violence differs from their cisgender, heterosexual peers and may have unique complicating factors. (Reaffirm HOD Policy)

Fiscal Note: Less than $1,000
REFERENCES


REPORT 2 OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH (I-18)
FDA Expedited Review Programs and Processes
(Resolution 201-I-17)
(Reference Committee K)

EXECUTIVE SUMMARY

Objective. To examine expedited FDA drug approval programs or processes in place in the United States, including so-called fast track, accelerated approval, designated breakthrough therapies, and “priority review” for drugs and biologics, and whether the operation of such programs needs to be re-examined or modified.

Methods. English-language reports were selected from a PubMed and Google Scholar search from 1992 to August 2018, using the MeSh terms “*biomarkers,” “*surrogate end points,” “drug approval/*methods/*statistical outcomes/*legislation & jurisprudence, *validation,” “United States Food and Drug Administration,” “product surveillance/*postmarketing” and “government regulation,” combined with the text terms “clinical trials,” “treatment outcome,” “accelerated approval,” “breakthrough therapy,” “priority review,” and “fast track.” Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the U.S. Food and Drug Administration (FDA).

Results. Different programs have been put in place over the last 25 years by the FDA and Congress to expedite the review of promising new therapies and to approve drugs for initial marketing based on lower evidentiary standards, including the use of surrogate markers. The use of surrogate endpoints has assumed increasing importance as approximately 40% of pivotal clinical trials for drug approvals or new indications rely on them. More than 60% of fast track approvals are now characterized as specialty drugs. Priority review processes have been successful in reducing the average application review time. One overarching theme is the strength of evidence relied on by the FDA to support marketing of new drugs. While various analyses have been conducted over different time frames examining the impact of expedited review programs on drug safety and efficacy, the most comprehensive review found that, for the most part, the use of surrogate endpoints has been successful, and the majority of sponsors have approached the conduct of confirmatory studies in a timely manner, although some failures do exist.

Conclusion. Over the years, the FDA has implemented various approaches to expedite the review and approval of new drug and biologic applications, as well as new indications for existing products. Accelerated approval, fast track, prior review, and breakthrough therapy designations have been developed, but these expedited programs differ and should not be lumped together from a scientific, public health, or policy point of view. Key variables include the requirement for post-approval studies for drugs marketed under accelerated approval, whether a surrogate endpoint that has not been validated is used to support approval, and the need to confirm clinical benefit and the risk-benefit profile for drugs approved based on limited evidence, regardless of their review designation. While it is important for the agency to retain regulatory flexibility, and many positive aspects of expedited programs are apparent, some changes should be made to improve implementation, establish the value of surrogate endpoints, and provide more transparency for clinicians and their patients.
INTRODUCTION

Resolution 201-I-17, “Improving FDA Expedited Approval Pathways,” introduced by the Resident and Fellow Section and referred by the House of Delegates asked:

That our American Medical Association work with U.S. Food and Drug Administration (FDA) and other interested stakeholders to design and implement via legislative action (including ensuring appropriate FDA staffing) a process by which drugs which obtain FDA approval via the Fast Track, Accelerated Approval, or Breakthrough Therapy pathways be granted FDA approval on a temporary basis not to exceed 5 years, pending further evidence of safety and efficacy that is at the level set for the standard drug approval process; and,

That our AMA work with the FDA and other interested stakeholders in improving the process by which drugs are selected for the expedited pathway to improve the prevalence of these drugs that are classified as “specialty drugs.”

This report examines expedited FDA drug approval processes in place in the United States, including so-called fast track, accelerated approval, designated breakthrough therapies, and “priority review” for drugs and biologics. Such programs are “intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening conditions” (especially when no satisfactory alternative therapies exist), and “be available to patients as soon as it can be concluded that the therapies’ benefits justify the risks.”1-3 Accordingly, under the current regulatory structure for approval of new chemical entities or new indications (efficacy supplements), the specific drug development program, including eligibility for expedited programs, is determined by the seriousness and prevalence of the disease, availability of existing treatments, and evidence that the drug can offer significant improvement compared with available therapies.

Two specific topics, one referred to in the resolution (specialty drugs) and the other which also impacts the FDA’s review of new drug applications (user fees) are not specifically evaluated in this report. The FDA does not define “specialty drugs” nor is it a term found in regulations or statute. The term specialty drug is generally used for complex, high-cost medications; they are often derived from a living source, characterizing them as biologics. Historically, they have been used to treat serious, chronic conditions such as rare diseases, cancer, rheumatoid arthritis, and multiple sclerosis. In recent years, specialty drugs have targeted more common conditions such as high cholesterol, asthma and hepatitis C, significantly increasing the potential pool of patients that
receive them. Specialty drugs are not stocked at most pharmacies, are often injectable medications, and may have unique storage or shipment requirements, such as refrigeration. These medications usually require additional patient education and support beyond traditional dispensing and counseling activities to maintain adherence and ensure patient safety. The growth in specialty drugs has been exponential. In the past four years nearly 100 new specialty drugs were launched, and in the same time there were 80 supplemental approvals establishing new indications for existing products. Based on the number and high degree of success in getting such drugs approved, special attention to these types of drugs, with respect to drug development, is not warranted. Concerns also have been expressed that the high cost of many specialty drugs is not justified when compared with their clinical benefits. Cost is a variable that is not under the purview of the FDA.

The Prescription Drug User Fee Act (PDUFA), first enacted in 1992, established the current framework by which pharmaceutical manufacturers help fund the FDA by submitting a fee along with their application. Monies derived from so-called “user fees” have been used to expand FDA staffing dedicated to the review of new drug (NDA) and biological license applications (BLA) and efficacy supplements (sNDA); the latter are submitted when sponsors seek approval to add a new indication to prescription drug labeling. A comparable user fee process also is now in place for abbreviated new drug applications (ANDA) that govern generic drug approval. Because user fees support FDA drug reviews in general, and are not an expedited program or process per se, the impact of PDUFA review times on drug safety and patient benefits is not further evaluated in this report.

METHODS

English-language reports were selected from a PubMed and Google Scholar search from 1992 to August 2018, using the MeSh terms “*biomarkers,” “*surrogate end points,” “drug approval/*methods/*statistical outcomes/*legislation & jurisprudence, *validation,” “United States Food and Drug Administration,” “product surveillance/*postmarketing” and “government regulation,” combined with the text terms “clinical trials,” “treatment outcome,” “accelerated approval,” “breakthrough therapy,” “priority review,” and “fast track.” Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet site of the US Food and Drug Administration (FDA).

CURRENT AMA POLICY

AMA Policy H-100.992, “FDA,” supports the concept that an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute. The statute regarding evidentiary standards for drug approval was modified in 1997 permitting FDA to approve a drug product “upon determination that the product has an effect on a clinical endpoint or on a surrogate endpoint that is reasonably likely to predict clinical benefit.” The evidence should be evaluated by the agency in consultation with its Advisory Committees and expert extramural advisory bodies, and any risk-benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications.

Policy D-100.978, “FDA Drug Safety Policies,” directs the AMA to monitor and respond, as appropriate, to implementation of the drug safety provisions of the FDA Amendments Act of 2007 (FDAAA; P.L. 110-85). This directive was related primarily to the fact that FDA authorities around Risk Evaluation and Mitigation Strategies were strengthened by the 2007 law.
DESCRIPTION OF EXPEDITED DRUG AND BIOLOGIC APPROVAL PROCESSES

Regular approval was the only FDA approval pathway until 1992. Largely in response to the HIV/AIDS epidemic in the mid-late 1980s, the FDA institutionalized approaches by which certain drugs, including antiretroviral products at the time, could be initially approved based on less rigorous data, including the use of surrogate endpoints.

Accelerated Approval

Conceptualized in the 1980s, initially implemented in 1992 and further refined in 2012, the accelerated approval pathway for drugs and biologics is described in 21CFR parts 314 (subpart H) and 602 (subpart E) and contained in Section 506(c) of the Food Drug and Cosmetic (FD&C) Act.\(^5\)\(^-\)\(^7\) It has been primarily used in settings where the course of the disease is long and an extended period would be required to measure the intended clinical benefit (e.g., decreased mortality from HIV infection, increased overall survival from cancer). Qualifying criteria are a drug that treats a serious condition, generally provides a meaningful advantage over available therapies and demonstrates an effect on a “surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality.” Furthermore, the surrogate endpoint is reasonably likely to predict an effect on “some other clinical benefit (i.e., an intermediate clinical endpoint), considering the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.” The accelerated approval designation requires post-approval testing to verify efficacy and confirm the anticipated risk-benefit profile. From 2000 to 2103, 37 new drugs were granted accelerated approval, or about 10% of new molecular entities (NMEs).\(^8\)

A drug marketed under accelerated approval can be subject to expedited withdrawal if the surrogate endpoint(s) turns out to be faulty. The FDA maintains a list of drugs that have been withdrawn due to safety concerns or lack of efficacy.\(^9\) Many of these products predate 1992. Since 1992 about 25 drugs have been withdrawn from the market, most of which had gone through regular approval. A limited number of drugs marketed under accelerated approval have had their approval for specific indications withdrawn (see below).

Surrogate Endpoints. A surrogate is “a laboratory measurement or physical sign that is used in therapeutic trials as a substitute for a clinically meaningful endpoint that is a direct measure of how a patient feels, functions, or survives and is expected to predict the effect of the therapy.”\(^10\) Such measures are not intrinsically beneficial to patients, but are relied on to predict the benefits of treatment in the absence of data on patient-relevant final outcomes based on a “reasonably likely” standard. The use of surrogate endpoints allows for clinical trials with reduced sample size and shorter duration, thereby reducing expense and speeding patient access to new therapies. For most drugs marketed under accelerated approval, requiring the endpoint to be overall survival is not practical and may not be ethical.\(^11\)

Approval of a drug based on a surrogate endpoint introduces uncertainty about the drug’s true clinical benefit and this degree of uncertainty must be considered acceptable in order for the new drug or indication to be approved. Different scenarios exist in which a treatment may significantly affect a surrogate marker, but not the clinically significant endpoint. The strength of evidence for validating a surrogate marker is based on: (1) the biological plausibility of the relationship between the surrogate marker and patient outcomes; (2) epidemiologic evidence on the predictive value of the surrogate for the clinical outcome of interest; and (3) clinical trial level data confirming that the response of the surrogate marker to treatment corresponds to the effects of the treatment on the clinical outcome.\(^12\) Optimally, the strength of the surrogate-survival correlation would already be
established; however, many surrogate endpoints used during the drug approval process are not validated at the time. To validate all surrogate endpoints ahead of time would require several trials to be conducted on a specific research question, essentially defeating the purpose of the accelerated approval pathway.

The Use of Surrogate Endpoints for Drug Approval. Surrogate endpoints have assumed increasing importance as approximately 40% of pivotal trials constituting the basis for approval of NMEs and/or new indications for existing drugs are based on surrogate endpoints, with a high percentage of these being for oncology drugs.12,13

Several studies have been published examining the use of surrogate endpoints and accelerated approval of oncology drugs over the past 25 years.14-16 Two snapshots covered the periods from 1994-2004 and 2004-2011, with a few others covering different time periods.16,17 A comprehensive review of oncology drugs approved as NMEs and for new indications via accelerated approval (n=93) was recently published covering the period from the inception of the program (1992) through May 2017 and is the focus of the following discussion.16

Twenty-eight percent of accelerated approvals were supported by randomized controlled trials (RCTs), with single arm trials accounting for the remainder; the median patient population for determining efficacy was 143. Seven RCTs used time to progression as the end point and four used disease-free survival; the remainder of both RCTs and single arm trials (87%) used response rate (i.e., tumor burden) as the endpoint. Approximately 55% of the approvals have fulfilled their post-marketing requirements and verified benefit in a median 3.4 years after approval, based on measurement of progression-free survival or time to progression (i.e., disease control) (39%), overall survival (29%), response rate (26%) or disease-free recurrence or progression (6%). Most of the success stories had ongoing confirmatory trials planned and underway at the time of accelerated approval. Forty percent of accelerated approvals are still in the process of completing confirmatory trials and verifying clinical benefit; FDA approval was subsequently withdrawn for five new indications. Most of the unfulfilled commitments represent recent approvals (median time on the market = 18 months), although some outliers exist; eight of such products have been on the market for more than 5 years, mostly in rare patient populations. While one criticism of the accelerated approval pathway is the smaller sample size, review of documentation supporting accelerated approval indicates that the safety database is usually larger, about double the efficacy database.16 “The safety database includes patients “treated with the drug regardless of age, condition, or volunteer status.”16 If the accelerated approval is for a new indication of an already-approved drug then more expansive safety information and postmarketing data are already available. Only one cancer drug approved under accelerated approval has been withdrawn from the market because of both efficacy and safety issues (gemtuzumab ozogamicin), and this drug was later reapproved for a narrower population.19

Several trial-level analyses have “quantified the association between surrogate endpoints and overall survival, with one study finding that nearly 50% of meta-analyses reported correlation between surrogate outcomes and overall survival exceeding 0.7. On average surrogate endpoints are positively correlated with survival.”20

Fast Track Designation

The current fast track designation is defined in section 506(b) of the FD&C, as amended by the 1997 Food and Drug Modernization Act (section 112) and 2012 Food and Drug Administration Safety and Innovation Act (FDASIA) (section 109). This designation was designed to facilitate the development, and expedite the review of drugs to treat serious conditions and fill an unmet...
Some critics maintain that the term “unmet medical need” has been overused and is too imprecise. This pathway also is available for drugs that have been designated as a qualified infectious disease product. Fast track allows for approval based on preliminary evidence such as Phase 2 clinical studies (rarely Phase 1). A request for fast track designation can be filed with the investigational new drug application (IND) or after, but ideally before the pre-NDA or BLA meeting; the timeline for an FDA decision is within 60 calendar days of receipt of the request.

Actions to expedite development and review include more frequent interactions with the review team to discuss, in part, study design, the extent of safety data required to support approval, dose-response concerns and use of biomarkers, and a “rolling review” where parts of the application can be acted on when they are ready, in sequence. Drugs with fast track designation also could be eligible for priority review if such a request is supported by sufficient data when the NDA, BLA, or efficacy supplement submission is submitted. Fast track designations can be rescinded if qualifying criteria are not met.

From 2000 to 2013, the FDA approved 82 drugs under the fast track designation, or approximately 22% of the NME’s approved during the same time period. More than 60% of the fast track approvals were characterized as specialty drugs by the authors of this study.

**Breakthrough Therapy**

Described in Section 506(a) of the FD&C Act, the breakthrough therapy designation was created by the 2012 FDASIA to expedite the development and review of drugs which may demonstrate substantial improvement over available therapy. Qualifying criteria are that a drug is intended to treat a serious condition and preliminary clinical evidence indicates that the drug may demonstrate “substantial improvement on a clinically significant endpoint over available therapies.” The timeline for FDA response is the same as fast track and priority designations. In contrast to the fast track designation which could include theoretical or non-clinical data, a breakthrough designation requires clinical evidence which is sufficient to demonstrate substantial improvement in safety or effectiveness over available therapies, but additional evidence is still required for final approval. Determining if the “substantial improvement” criterion is met is a matter of judgement, and the evidence that is relied on for approval of drugs with this designation is heterogenous. This designation triggers intensive guidance on the drug development program beginning as early as Phase 1, FDA commitment involving senior FDA managers, a rolling review of the application and eligibility for priority review designation.

**Priority Review**

This process was established by the 1992 PDUFA to improve the efficiency of NDA reviews for NMEs. A priority review designation can be assigned to applications for drugs “that treat serious conditions and provide significant improvements in the safety or effectiveness of the treatment, diagnosis, or prevention of serious conditions compared to available therapies.” A priority review designation is assigned at the time of the NDA, BLA or efficacy supplement filing. Priority review can be granted to applications for drugs with fast track or breakthrough therapy designation, or to applications submitted for review under accelerated approval. That decision is based on the information and data available at the time the application is submitted.

The timeline for FDA response is the same as fast track designations with a shorter timeframe for reviewing the application versus standard review cycles (6 months compared with the 10-month target for the latter). From FY 2007 through FY 2016, the (average) median time to application approval was 11.4 months for standard review compared with 7.9 months for priority review.
CLINICAL TRIAL EVIDENCE AND EXPEDITED REVIEW PROGRAMS

A Perspective on New Drug Safety-Related Issues

One study conducted on postmarket safety outcomes for all NMEs (n=278) approved from 2002-2014 demonstrated that safety updates to the product labeling were the rule rather than the exception. At least one safety update was added to 195 (70.1%) of the products, most commonly between the 2nd and 8th year after marketing. Safety information was added earlier after marketing for drugs approved with a fast-track designation or under an accelerated approval using a surrogate end point; safety issues also were more likely to arise for drugs with a fast track designation.

Evidentiary Standards

Another perspective on drugs approved via expedited reviews is to examine the strength of evidence accompanying market approvals, which clearly has important implications for patients, physicians, and payers. Concern has been expressed about the potential lack of systematic monitoring for confirmation of effectiveness for drugs that have been approved based on limited evidence, compared with standard approvals.

One recent review of cancer drugs approved from 2006-2016 found that when RCTs were lacking, approved indications were more likely to be based on accelerated approval, receive a breakthrough designation or have a companion diagnostic test. Indications not supported by RCTs had higher odds of post approval safety changes, but not major modifications in indications and dosage, warnings and precautions, boxed warnings, or contraindication sections of the labeling.

Analysis of all drugs approved by the FDA from 2005-2012 revealed that most indications were supported by at least 1 RCT, although more than one-third of indications were approved based on a single pivotal efficacy trial. Substantial variation existed in terms of the comparators and endpoints, trial duration, number of participants, and completion rates. Surrogate endpoints served as the primary outcome for 91 of 206 (44%) of the approved indications.

From 2005-2014, 295 supplemental NDAs for new indications were submitted. Thirty percent of these were supported by efficacy trials with an active comparator and 32% used a clinical endpoint. Among those expanding the patient population (almost all pediatric), only 11% used an active comparator, with 22% using a clinical endpoint.

DISCUSSION

Over the years, the FDA has implemented various approaches to expedite the review and approval of new drug and biologic applications, as well as new indications for existing products. Under the current regulatory structure, the specific drug development program, including eligibility for expedited programs, is determined by the seriousness and prevalence (or rarity) of the disease, availability of existing treatments, and evidence that the new drug can offer significant improvement compared with available therapies and/or otherwise address an unmet medical need. Accelerated approval, fast track, priority review, and breakthrough therapy designations have been developed to consider and address these variables. These expedited programs differ and should not be lumped together from a scientific, public health, or policy point of view. Key variables include the requirement for post-approval studies for drugs marketed under accelerated approval, whether a surrogate endpoint that has not been validated is used to support approval, and the need to confirm clinical benefit and the risk-benefit profile for drugs approved based on limited evidence, regardless of their review designation.
It has been argued that the process of approving medications based on more limited evidence, including fewer patients and patient years of exposure, makes the process of reducing healthcare disparities costlier. Earlier drug approval reduces the power of studies to detect difference in risk and benefit in relevant subgroups and could direct the burden of medical uncertainty toward groups of people who are often disadvantaged. It may be advisable for the FDA to encourage that confirmatory trials enable appropriate sub-group analyses that were not possible during initial, lower-powered studies. Accelerating drug approval shifts the burdens of uncertainty away from clinical trial participants (who have undergone informed consent) to others who are exposed to the treatment under different conditions, socializing the costs of uncertainty while pharmaceutical companies profit from new drug development. The relevant question is “whether earlier access to drugs, driven by changes in regulatory policy or growing reliance on surrogate endpoints, benefits or harms patients.”

Confirmatory studies are needed for drugs approved based on limited evidence to avoid exposing patients to potentially unsafe or ineffective therapies. Even the use of uncertain surrogate endpoints is not problematic if confirmatory studies reliably demonstrate meaningful clinical endpoints. A report from the Government Accountability Office, in referring to the FDA’s activities in this area, concluded that “the agency needs to clarify the conditions under which it would use its authority to expedite the withdrawal of drugs granted accelerate approval,” when confirmatory studies are not conducted in a timely manner or fail to confirm predicted benefits.

Over the past 15 years, most accelerated approvals were for oncologic drugs, and that experience is instructive. The accelerated approval of bevacizumab for breast cancer has been held up as a prime example of harm, because it was approved based on the endpoint of progression-free survival, but eventually this drug was shown to not increase overall survival. However, “clear and convincing evidence” has emerged from phase 2 (and some phase 1) trials leading to marketing approval of new chemical entities within 2-3 years accounting for “advances in treatment for molecular subsets of non-small cell lung cancer, melanoma, chronic leukemia, breast cancer, and acute myeloid leukemia,” among others.

Although critics have condemned a lack of “improved survival” as the optimal endpoint for clinical trials, there has been a “steady improvement in U.S. cancer mortality and survival over the past 2 decades” in part because of new treatments, but also better screening and early detection. Nevertheless, more than half of oncologic drugs marketed under accelerated approvals relied on a surrogate endpoint that was chosen in the absence of any formal analysis of the strength of the surrogate-survival connection. This observation reinforces the need for timely determination of the predicted clinical benefit and confirmation of the risk-benefit profile.

Comprehensive evaluation of oncologic drugs marketed under accelerated approval confirms that satisfactory progress has been made on confirmatory trials. By balancing risk, accounting for uncertainty, and operating under a paradigm of regulatory flexibility, existing FDA expedited pathways can ensure early access to, and appropriate use of new drugs and biologics, including specialty drugs. The Institute of Medicine recommended that the FDA should “implement a benefit and risk assessment and management plan that would summarize the FDA’s evaluation of drug’s risk-benefit profile in a single document and that would be continuously updated” during the life-cycle of the drug on the market. While it is important for the agency to retain regulatory flexibility, and mostly positive aspects of expedited programs are apparent, some changes should be made to improve implementation, establish the value of surrogate endpoints, and provide more transparency for physicians and their patients on the level of evidence used for marketing approval.
RECOMMENDATION

The Council on Science and Public Health recommends that Policy H-100.992 be amended by addition and deletion to read as follows in lieu of Res-201-I-17, and the remainder of the report be filed:

(1) Our AMA reaffirms its support for the principles that:

(a) an FDA decision to approve a new drug, to withdraw a drug's approval, or to change the indications for use of a drug must be based on sound scientific and medical evidence derived from controlled trials and/or postmarket incident reports as provided by statute;
(b) the evidence for drug approval should be evaluated by the FDA, in consultation with its Advisory Committees and expert extramural advisory bodies;
(c) expedited programs for drug approval serve the public interest as long as sponsors for drugs that are approved based on surrogate endpoints or limited evidence conduct confirmatory trials in a timely fashion to establish the expected clinical benefit and predicted risk-benefit profile;
(d) confirmatory trials for drugs approved under expedited programs should be planned and underway at the time of expedited approval;
(e) the FDA should pursue having in place a systematic process to ensure that sponsors adhere to their obligations for confirmatory trials, and Congress should establish a firmer threshold to trigger expedited withdrawal when sponsors fail to fulfill their postmarketing study obligations;
(d-f) any risk-benefit analysis or relative safety or efficacy judgments should not be grounds for limiting access to or indications for use of a drug unless the weight of the evidence from clinical trials and postmarket reports shows that the drug is unsafe and/or ineffective for its labeled indications; and,
(g) FDA should consider a simple system to assign a grade for each approval of prescription drugs occurring via expedited programs in order to signal, and provide in a transparent manner, the quality of clinical trial evidence used to establish safety and effectiveness, and whether confirmatory trials are required for labeled indications.

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

(3) It is the position of our AMA that the Food and Drug Administration should not permit political considerations or conflicts of interest to overrule scientific evidence in making policy decisions; and our AMA urges the current administration and all future administrations to consider our best and brightest scientists for positions on advisory committees and councils regardless of their political affiliation and voting history.

Fiscal Note: Less than $500
REFERENCES


2. 21 CFR 312.300(b)(1).


8. Kesselheimn AS, Yongtian TT, Darrow JJ, Avorn J. Existing FDA pathways have potential to ensure early access to, and appropriate use of, specialty drugs. Health Affairs. 2014;10:1770-78.

9. 21 CFR. §216.24. Drug products withdrawn or removed from the market for reasons of safety or effectiveness.


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”;

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; 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”; and

Whereas, There is a systemic lack of reproducibility among published biomedical research studies, as highlighted by a recent report finding that nearly 70% of researchers were unable to reproduce another scientist’s results; 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; 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; 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;" therefore be it

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1 AMA Code of Medical Ethics Opinion E-7.2.1 Principles for Disseminating Research Results
5 Nosek BA, et al. The Preregistration Revolution.
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: CLR PD 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 website 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

Whereas, There is currently no national consensus on EM resident education for sexual assault examinations, leading to EM physicians who are undertrained to complete the MFE;\(^9\) 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; and

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

Whereas, Studies show that children perceive food products with nutrient claims on their FOP label as healthier; 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, 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{16} 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; 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; 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; 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; and

References:

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;\textsuperscript{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;\textsuperscript{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\%;\textsuperscript{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;\textsuperscript{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;\textsuperscript{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;\textsuperscript{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;\textsuperscript{22,23,24} and


\textsuperscript{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.,” \textit{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/CLRDP 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
and

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;\(^{10}\) 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;\(^{11}\) 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;\(^{12}\) 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;\(^{13},^{14}\) 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;\(^{15},^{16}\) and

Whereas, The average application fees to obtain a birth certificate and passport in the U.S. are $15.81 and $97, respectively;\(^{17}\) and

Whereas, A national study found that 36% of homeless individuals could not obtain a photo identification because they could not afford it;\(^{18}\) 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;\(^{19},^{20},^{21},^{22},^{23}\) therefore be it


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-being; 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)
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/CLRDPD 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 addicted 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

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

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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.

Received: 09/28/18
AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES

Resolution: 915

Introduced by: American College of Emergency Physicians
Subject: Mandatory Reporting
Referred to: Reference Committee K
(Darlyne Menscer, MD, Chair)

Whereas, In general, mandatory reporting for conditions should seek to mitigate against risk to
others in society as a result of their interaction with the patient triggering mandatory reporting,
such as in cases of infectious disease, or should assist uniquely vulnerable populations, such as
victims of child abuse or domestic violence; and

Whereas, Physician reporting requirements are increasingly being mandated for conditions that
do not pose a public health threat or serve to protect vulnerable populations, including
California’s recent passage of a law requiring physicians and other health care providers
diagnosing or providing treatment to Parkinson’s disease patients to report each case of
Parkinson’s disease to the state Department of Public Health1; and

Whereas, Zealous commitment to alleviate specific conditions should not dictate broad-based
public mandates; and

Whereas, Compliance with mandatory reporting requirements substantially adds to the
significant and growing administrative burden borne by physicians and other health care
providers; therefore be it

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

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

Received: 10/10/18

References:
1 California HSC-Division 102-Part 2-Chapter 1.6
https://leginfo.legislature.ca.gov/faces/codes_displayText.xhtml?lawCode=HSC&division=102.&title=&part=2.&chapter=1.6.&article=
Whereas, The Food and Drug Administration (FDA), under the family smoking prevention and
tobacco control act, has authority to regulate all tobacco products, including electronic nicotine
delivery systems (ENDS) such as e-cigarettes; and

Whereas, END use has dramatically increased among youth; and

Whereas, Youth report that END flavors are a compelling reason youth try and continue to use
END products; and

Whereas, FDA Commissioner Scott Gottlieb MD has called the youth rise in e-cigarette use an
“epidemic”; and

Whereas, Several flavoring agents currently use in END products, including diacetyl,
2,3 pentanedione, acetoin, cinnamaldehyde, banzaldehyde, eugenol, vanillin/ethyl
vanillin, and menthol, have known toxicity when exposed to the lung; and

Whereas, Other flavoring agents have been tested for oral and digestive tract exposure but
have not yet been tested adequately for inhalation and respiratory exposure; therefore be it
RESOLVED, That our American Medical Association call for the immediate ban on flavoring
agents in ENDS and other tobacco products that have known respiratory toxicity including but
not limited to diacetyl, 2,3 pentanedione, acetoin, cinnamaldehyde, banzaldehyde, eugenol,
vanillin/ethyl vanillin, and menthol (Directive to Take Action); and be it further

RESOLVED, That our AMA urge the Food and Drug Administration (FDA) to require
comprehensive testing of flavoring agents used in electronic nicotine delivery systems (ENDS)
and other tobacco products to assess the potential negative health effects of chronic exposure
to these flavoring agents. (Directive to Take Action)

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

Received: 10/11/18
AMERICAN MEDICAL ASSOCIATION
HOUSE OF DELEGATES

Resolution: 917
(I-18)

Introduced by: American Thoracic Society, Society of Critical Care Medicine,
American College of Chest Physicians

Subject: Protect and Maintain the Clean Air Act

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

Whereas, The scientific literature clearly documenting that exposure to air pollution results in significant adverse health effects including premature mortality, reduced lung function, exacerbation of respiratory disease, missed school and work days, increased medication use and other health effects; and

Whereas, The Clean Air Act, which has been implemented and enforced by the Environmental Protection Agency, has made significant improvements in US air quality that have led to measurable improvements in public health; and

Whereas, The “New Source Review” section of the Clean Air Act (CAA) is an important section of the law that requires that when a major pollution emitting facility makes changes to its equipment or operations that are expected to result in increased annual pollution emissions, the facility must install pollution control emissions equipment; and

Whereas, Coal and oil-fired power plants are a major source of both greenhouse gas emissions and air pollution emissions in the U.S.; and

Whereas, The Administration has issued a proposed rule, called Affordable Clean Energy rule, to regulate greenhouse gas (GHG) emissions from coal and oil-fired power plants that would result in a mere 1.5% reduction in GHG emissions, but would allow power plants to increase annual emissions of other pollutants including particulate matter, sulfur oxides and nitrogen oxides without having to meet the CAA’s New Source Review requirements; and

Whereas, The increase in annual air pollution emissions will result in an increase in adverse health effects for those living in the US; and

Whereas, The EPA estimates implementation of the proposed rule will result in an additional 1,400 premature deaths annually, 48,000 additional asthma attacks, and 21,000 missed school days posing a significant impact on an individual’s quality of life and financial stability; and

Whereas, Cost effective pollution-reduction technology exists today and is in operation at power plants across the US; therefore be it

RESOLVED, That our American Medical Association oppose provisions of the Affordable Clean Energy proposed rule that would allow power plants to avoid complying with new source review requirements to install air pollution control equipment when annual pollution emissions increase (New HOD Policy); and be it further
RESOLVED, That our AMA send a letter to the Environmental Protection Agency (EPA) expressing our opposition to EPA’s Affordable Clean Energy rule and its proposed amendments of the New Source Review requirements under the Clean Air Act. (Directive to Take Action)

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

Received: 10/11/18

RELEVANT AMA POLICY

Support the Health Based Provisions of the Clean Air Act H-135.950
Our AMA (1) opposes changes to the New Source Review program of the Clean Air Act; (2) urges the Administration, through the Environmental Protection Agency, to withdraw the proposed New Source Review regulations promulgated on December 31, 2002; and (3) opposes further legislation to weaken the existing provisions of the Clean Air Act.
Citation: (Res. 417, A-03; Reaffirmation A-05; Reaffirmation I-11)

Clean Air H-135.991
(1) The AMA supports setting the national primary and secondary ambient air quality standards at the level necessary to protect the public health. Establishing such standards at the level necessary to protect the public health. Establishing such standards at a level "allowing an adequate margin of safety," as provided in current law, should be maintained, but more scientific research should be conducted on the health effects of the standards currently set by the EPA. (2) The AMA supports continued protection of certain geographic areas (i.e., those with air quality better than the national standards) from significant quality deterioration by requiring strict, but reasonable, emission limitations for new sources. (3) The AMA endorses a more effective hazardous pollutant program to allow for efficient control of serious health hazards posed by airborne toxic pollutants. (4) The AMA believes that more research is needed on the causes and effects of acid rain, and that the procedures to control pollution from another state need to be improved. (5) The AMA believes that attaining the national ambient air quality standards for nitrogen oxides and carbon monoxide is necessary for the long-term benefit of the public health. Emission limitations for motor vehicles should be supported as a long-term goal until appropriate peer-reviewed scientific data demonstrate that the limitations are not required to protect the public health.
Citation: (BOT Rep. R, A-82; Reaffirmed: CLRPD Rep. A, I-92; Amended: CSA Rep. 8, A-03; Reaffirmation I-06; Reaffirmed in lieu of Res. 509, A-09; Reaffirmation I-09; Reaffirmation A-14)
Whereas, Anaphylactic food allergies continue to increase in prevalence; and

Whereas, An anaphylactic food allergy may be fatal; and

Whereas, There has been a documented fatal anaphylactic food reaction in a teenager who unsuspectingly ate from packaging that resembled packaging of other, non-allergenic, food products; and

Whereas, Current Food and Drug Administration (FDA) food labeling guidelines are inadequate to prevent accidental allergen exposure when products are contained in familiar packaging that usually does not contain common allergens; therefore be it

RESOLVED, That our American Medical Association petition the Food and Drug Administration to pursue more obvious labeling on food packaging containing the eight most common food allergens: milk, eggs, peanuts, tree nuts, wheat, soy, fish and crustacean shellfish. (Directive to Take Action)

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

Received: 10/09/18
RELEVANT AMA POLICY

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)

Preventing Allergic Reactions in Food Service Establishments D-440.932
Our American Medical Association will pursue federal legislation requiring restaurants and food establishments to: (1) include a notice in menus reminding customers to let the staff know of any food allergies; (2) educate their staff regarding common food allergens and the need to remind customers to inform wait staff of any allergies; and (3) identify menu items which contain any of the major food allergens identified by the FDA (in the Food Allergen Labeling and Consumer Protection Act of 2004) and which allergens the menu item contains.
Citation: (Res. 416, A-15)
Whereas, Indiana has suffered the scourge of opioid abuse, addiction, overdose and death. There has been much suffering among family and friends of Hoosier opioid users; and

Whereas, Clark County, IN, has enjoyed some success in lowering overdose deaths with several identified strategies that help mitigate the issue; and

Whereas, Huntington, WV, has enjoyed more success in its strategies to combat opioids. They can serve as an example of best practices, and one of the most effective tools is an opioid overdose team. This team visits the home of someone who has been discharged from the emergency department with a diagnosis of opioid overdose. This visit occurs typically on the day of the overdose. The goal of the visit is to educate the individual about all the services available for opioid users in Huntington and its associated Cabell County. The most important information presented relates to options for drug rehabilitation. Encouragement and support are also part of the message; and

Whereas, The success of the West Virginia program is also rooted in generous funding from the city, county and state for the services described, as well as in a strong sense of community, collaboration and cooperation between the organizations dealing with this difficult issue; and

Whereas, Local and state political leaders and legislative bodies should support such a program with adequate funding to help ensure its success. We are dealing with a pay-now or pay-more-later situation. Premature death of an individual from an opioid overdose has economic consequences in the millions of dollars per individual, as well as stress and psychological effects on the family. There is also an increase in costs due to more crime, policing, court cases and incarcerations; therefore be it.
RESOLVED, That our American Medical Association review the following opioid mitigation strategies based on their effectiveness in Huntington, WV, and Clark County, IN, and provide feedback concerning their utility in dealing with opioids:

(1) The creation of an opioid overdose team that decreases the risk of future overdose and overdose death, increases access to opioid-related services and increases the likelihood that an individual will pursue drug rehabilitation.

(2) A needle exchange program that is open multiple days a week and is mobile offers not only a source for needles but also Narcan, other supplies, health care and information.

(3) The creation of a drug court that allows a judge to have greater flexibility in determining the legal consequences of an arrest for an opioid-related crime. It also allows for the judicial patience necessary to deal with the recidivism of this population.

(4) Offering more acute-care inpatient drug rehab beds, although those ready for treatment need to be willing to travel significant distances to get to a treatment bed.

(5) Make available Narcan intranasal spray OTC through pharmacies and the syringe exchange, overdose team, etc.

(6) Encourage prevention education in K-12 programs that uses multiple media with anti-drug messaging delivered in the school system but also in the home. (Directive to Take Action)

Fiscal Note: Estimated cost to implement resolution is $130K.

Received: 10/09/18

RELEVANT AMA POLICY

https://policysearch.ama-assn.org/policyfinder/search/opioids/relevant/1/
Whereas, The “CDC estimates that vaccination of children born between 1994 and 2013 will prevent 322 million illnesses; will help avoid 732,000 deaths; and will save nearly $1.4 trillion in total societal costs;" and

Whereas, Section 317 of the Public Health Service Act provides federal funding to cover vaccines for uninsured and underinsured individuals as well as those with insurance during times of emergency outbreaks; and

Whereas, The federal funding through the Section 317 program also serves a crucial role in vaccine development and improvement, conducting community outreach and education, and leading the responses to disease outbreaks; and

Whereas, The Section 317 program is different from the Vaccines for Children program in that Section 317 funded vaccines can be given to under-insured individuals receiving vaccines at a health care institution that is not a Federally Qualified Health Center nor deputized; and

Whereas, An independent study demonstrated that an increase in Section 317 funding by $10 per individual resulted in a 1.6 percent increase in vaccination coverage between 1997 and 2003; and

Whereas, In the Fiscal Year 2018 President’s Budget Proposal and House of Representatives Appropriations, $521,000,000 and $557,000,000, respectively, is appropriated for funding for the Section 317 Immunization program, a decrease from $607,000,000 allocated in Fiscal Year 2017; and

Whereas, While it is important for funding to remain, at minimum, the same; ideally, it would increase to support public health efforts at vaccination and safety during times of outbreaks across individual states and the country; therefore be it

RESOLVED, That our American Medical Association release a public statement of support for federal vaccination funding efforts such as Section 317, and actively advocate for sustained funding. (Directive to Take Action)
RELEVANT AMA POLICY

Financing of Adult Vaccines: Recommendations for Action H-440.860

1. Our AMA supports the concepts to improve adult immunization as advanced in the Infectious Diseases Society of America’s 2007 document "Actions to Strengthen Adult and Adolescent Immunization Coverage in the United States," and support the recommendations as advanced by the National Vaccine Advisory Committee’s 2008 white paper on pediatric vaccine financing.

2. Our AMA will advocate for the following actions to address the inadequate financing of adult vaccination in the United States:

   Provider-related
   a. Develop a data-driven rationale for improved vaccine administration fees.
   b. Identify and explore new methods of providing financial relief for adult immunization providers through, for example, vaccine company replacement systems/deferred payment/funding for physician inventories, buyback for unused inventory, and patient assistance programs.
   c. Encourage and facilitate adult immunization at all appropriate points of patient contact; e.g., hospitals, visitors to long-term care facilities, etc.
   d. Encourage counseling of adults on the importance of immunization by creating a mechanism through which immunization counseling alone can be reimbursed, even when a vaccine is not given.

   Federal-related
   a. Increase federal resources for adult immunization to: (i) Improve Section 317 funding so that the program can meet its purpose of improving adult immunizations; (ii) Provide universal coverage for adult vaccines and minimally, uninsured adults should be covered; (iii) Fund an adequate universal reimbursement rate for all federal and state immunization programs.
   b. Optimize use of existing federal resources by, for example: (i) Vaccinating eligible adolescents before they turn 19 years of age to capitalize on VFC funding; (ii) Capitalizing on public health preparedness funding.
   c. Ease federally imposed immunization burdens by; for example: (i) Providing coverage for Medicare-eligible individuals for all vaccines, including new vaccines, under Medicare Part B; (ii) Creating web-based billing mechanisms for physicians to assess coverage of the patient in real time and handle the claim, eliminating out-of-pocket expenses for the patient; (iii) Simplifying the reimbursement process to eliminate payment-related barriers to immunization.
d. The Centers for Medicare & Medicaid Services should raise vaccine administration fees annually, synchronous with the increasing cost of providing vaccinations.

State-related
a. State Medicaid programs should increase state resources for funding vaccines by, for example: (i) Raising and funding the maximum Medicaid reimbursement rate for vaccine administration fees; (ii) Establishing and requiring payment of a minimum reimbursement rate for administration fees; (iii) Increasing state contributions to vaccination costs; and (iv) Exploring the possibility of mandating immunization coverage by third party payers.
b. Strengthen support for adult vaccination and appropriate budgets accordingly.

Insurance-related
1. Provide assistance to providers in creating efficiencies in vaccine management by: (i) Providing model vaccine coverage contracts for purchasers of health insurance; (ii) Creating simplified rules for eligibility verification, billing, and reimbursement; (iii) Providing vouchers to patients to clarify eligibility and coverage for patients and providers; and (iv) Eliminating provider/public confusion over insurance payment of vaccines by universally covering all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines.
b. Increase resources for funding vaccines by providing first-dollar coverage for immunizations.
c. Improve accountability by adopting performance measurements.
d. Work with businesses that purchase private insurance to include all ACIP-recommended immunizations as part of the health plan.
e. Provide incentives to encourage providers to begin immunizing by, for example: (i) Including start up costs (freezer, back up alarms/power supply, reminder-recall systems, etc.) in the formula for reimbursing the provision of immunizations; (ii) Simplifying payment to and encouraging immunization by nontraditional providers; (iii) Facilitating coverage of vaccines administered in complementary locations (e.g., relatives visiting a resident of a long-term care facility).

Manufacturer-related
Market stability for adult vaccines is essential. Thus: (i) Solutions to the adult vaccine financing problem should not deter research and development of new vaccines; (ii) Solutions should consider the maintenance of vibrant public and private sector adult vaccine markets; (iii) Liability protection for manufacturers should be assured by including Vaccine Injury Compensation Program coverage for all ACIP-recommended adult vaccines; (iv) Educational outreach to both providers and the public is needed to improve acceptance of adult immunization.
3. Our AMA will conduct a survey of small- and middle-sized medical practices, hospitals, and other medical facilities to identify the impact on the adult vaccine supply (including influenza vaccine) that results from the large contracts between vaccine manufacturers/distributors and large non-government purchasers, such as national retail health clinics, other medical practices, and group purchasing programs, with particular attention to patient outcomes for clinical preventive services and chronic disease management.

Citation: (CSAPH Rep. 4, I-08; Reaffirmation I-10; Reaffirmation I-12; Reaffirmation I-14)

Reimbursement for Influenza Vaccine H-440.848
Our AMA: (1) will work with third party payers, including the Centers for Medicare and Medicaid Services, to establish a fair reimbursement price for the flu vaccine; (2) encourage the manufacturers of influenza vaccine to publish the purchase price by June 1st each year; (3) shall seek federal legislation or regulatory relief, or otherwise work with the federal government to increase Medicare reimbursement levels for flu vaccination and other vaccinations.
Citation: (CSAPH Rep. 5, I-12)
Assuring Access to ACIP/AAFP/AAP-Recommended Vaccines H-440.875

1. It is AMA policy that all persons, regardless of economic and insurance status, receive all Advisory Committee on Immunization Practices (ACIP)-recommended vaccines as soon as possible following publication of these recommendations in the Centers for Disease Control and Prevention's (CDC) Morbidity and Mortality Weekly Report (MMWR).

2. Our AMA will continue to work with the federal government, Congress, and other stakeholders to improve liability protection for vaccine manufacturers and health care professionals who provide immunization services and to examine and improve compensation mechanisms for patients who were legitimately injured by a vaccine.

3. Our AMA will continue to work with the federal government, Congress, and other appropriate stakeholders to enhance public opinion of vaccines and to monitor and ensure the continued safety of existing and newly approved vaccines (including providing adequate resources for post-approval surveillance) so as to maintain and improve public confidence in the safety of vaccines.

4. Our AMA will work with appropriate stakeholders, including vaccine manufacturers, vaccine distributors, the federal government, medical specialty societies, and third party payers, to guarantee a robust vaccine delivery infrastructure (including but not limited to, the research and development of new vaccines, the ability to track the real-time supply status of ACIP-recommended vaccines, and the timely distribution of ACIP-recommended vaccines to providers).

5. Our AMA will work with appropriate federal and state agencies and private sector entities to ensure that state Medicaid agencies and private insurance plans pay health care professionals at least the approved Relative Value Unit (RVU) administration Medicare rates for payment when they administer ACIP-recommended vaccines.

6. Our AMA will work with the Centers for Medicare and Medicaid Services (CMS) to address barriers associated with Medicare recipients receiving live zoster vaccine and the routine boosters Td and Tdap in physicians' offices.

7. Our AMA will work through appropriate state entities to ensure all health insurance plans rapidly include newly ACIP-recommended vaccines in their list of covered benefits, and to pay health care professionals fairly for the purchase and administration of ACIP-recommended vaccines.

8. Our AMA will urge Medicare to include Tdap (Tetanus, Diphtheria, Acellular Pertussis) under Medicare Part B as a national public health measure to help prevent the spread of Pertussis.

9. Until compliance of AMA Policy H-440.875(6) is actualized to the AMA's satisfaction regarding the tetanus vaccine, our AMA will aggressively petition CMS to include tetanus and Tdap at both the "Welcome to Medicare" and Annual Medicare Wellness visits, and other clinically appropriate encounters, as additional “triggering event codes” (using the AT or another modifier) that allow for coverage and payment of vaccines to Medicare recipients.

10. Our AMA will aggressively petition CMS to include coverage and payment for any vaccinations administered to Medicare patients that are recommended by the ACIP, the US Preventive Services Task Force (USPSTF), or based on prevailing preventive clinical health guidelines.

Citation: BOT Action in response to referred for decision Res. 524, A-06; Reaffirmation A-07; Appended: Res. 531, A-07; Reaffirmation A-09; Reaffirmed: Res. 501, A-09; Reaffirmation I-10; Reaffirmation A-11; Reaffirmed in lieu of Res. 422, A-11: BOT action in response to referred for decision Res. 422, A-11; Reaffirmation: I-12; Appended: Res. 227, I-12; Appended: Res. 824, I-14; Reaffirmed: Res. 411, A-17
Whereas, Over 29.7 million Americans live at or below 200 percent of the federal poverty level; and
Whereas, Food security, diversity, and accessibility significantly impact individual and community health; and
Whereas, A food desert is defined by the United States Department of Agriculture as a low-income census tract where a significant number or share of residents have low access to a full-service supermarket or grocery store, where low access is defined as residing more than 1 mile from a full-service grocery store in urban areas and more than 10 miles from a full-service grocery store in rural areas; and
Whereas, A food swamp can be characterized as areas where large relative amounts of energy-dense snack foods inundate healthy food options or geographic areas with disproportionate access to energy-dense, nutrient-poor foods; and
Whereas, A food mirage is a food environment distinct from food deserts in that healthy foods may be available, but prices are beyond the means of those living nearby, making them functionally equivalent to food deserts in that long journeys are needed to obtain food; and
Whereas, Food mirages are often invisible to conventional food desert assessment criteria due to their proximity to healthy food options and thereby causing an illusion of access; and
Whereas, Conventional food desert assessments can inaccurately assume that grocery store prices are reasonably similar, and that any full-service grocery store can serve consumers equally well as points of access to healthy foods; and
Whereas, Though grocery store food can be relatively affordable compared to those of other stores, it does not equate to being affordable for low-income residents who may be struggling to consistently put food on the table; and
Whereas, Not only is price at times the strongest motivator for deciding where one shops or if one is even able to shop, consideration for whether their choice stores accept federal assistance dollars further sways their decisions; and
Whereas, A food outlet’s choice of inventory and impact on a community’s food diversity are influenced heavily by community interest and consumer financial capability, and
Whereas, A food oasis is best described as “any place where people have the best possible access to healthy options and eating environments” where “access includes financial and physical access to healthy foods and drinks that are high quality, affordable, culturally acceptable, and meet the nutritional needs of the people in the community;” and

Whereas, Previous studies examining food oases effectively consider them the gold standard for communities to strive for; and

Whereas, American Medical Association (AMA) policies such as D-150.978 and 150.034MSS provide no guidance on identification of food oases, which makes it more difficult to differentiate between communities that may or may not have access to healthy, affordable food alternatives; and

Whereas, Although these AMA policies aim to address disparities secondary to functional access to food including cost, ethnic preferences, and education, these alone are unlikely to resolve the distinct challenges faced by food swamps and food mirages; and

Whereas, By accounting only for food deserts, which are measured in literature and policy by physical proximity to healthy foods, and omitting consideration of consumer socioeconomic or cultural factors, “food environment literature takes on a singular narrative and a narrow conceptual representation of the barriers people face to accessing food”; therefore be it

RESOLVED, That our American Medical Association work with appropriate stakeholders to advocate for the study of the national prevalence and impact of food mirages, food swamps, and food oases as food environments distinct from food deserts. (Directive to Take Action)

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

Received: 10/10/18

RELEVANT AMA POLICY

Sustainable Food D-150.978
Our AMA: (1) supports practices and policies in medical schools, hospitals, and other health care facilities that support and model a healthy and ecologically sustainable food system, which provides food and beverages of naturally high nutritional quality; (2) encourages the development of a healthier food system through tax incentive programs, community-level initiatives and federal legislation; and (3) will consider working with other health care and public health organizations to educate the health care community and the public about the importance of healthy and ecologically sustainable food systems.

Citation: (CSAPH Rep. 8, A-09; Reaffirmed in lieu of Res. 411, A-11; Reaffirmation A-12; Reaffirmed in lieu of Res. 205, A-12; Modified: Res. 204, A-13; Reaffirmation A-15)

Reform the US Farm Bill to Improve US Public Health and Food Sustainability H-150.932
Reform the US Farm Bill to Improve US Public Health and Food SustainabilityOur AMA supports the creation of a new advisory board to review and recommend US Farm Bill budget allocations to ensure any government subsidies are only used to help produce healthy food choices and sustainable foods, and that advisory committee members include physicians, public health officials and other public health stakeholders.

Citation: (Res. 215, A-13)
National Nutritional Guidelines for Food Banks and Pantries H-150.930

Our AMA: (1) supports the use of existing national nutritional guidelines for food banks and food pantries and (2) will promote sustainable sourcing of healthier food options and the dissemination of user-friendly resources and education on healthier eating for food banks and food pantries.

Citation: Res. 413, A-14; Appended: Res. 415, A-17

SOURCES


