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AMERICAN MEDICAL ASSOCIATION HOUSE OF DELEGATES (A-14)

Report of Reference Committee E

Jay A. Gregory, MD, Chair

Your Reference Committee recommends the following consent calendar for acceptance:

RECOMMENDED FOR ADOPTION

1. Council on Science and Public Health Report 1 – CSAPH Sunset Review of 2004 House Policies
2. Council on Science and Public Health Report 2 – Genomic-based Approaches to the Risk Assessment, Management and Prevention of Type 2 Diabetes
3. Council on Science and Public Health Report 4 – Biosimilar Product Approval and Marketing
4. Resolution 512 – Risk Evaluation and Mitigation Strategies (REMS) for Methadone
5. Resolution 513 – Antibiotic Use in Food-Producing Animals

RECOMMENDED FOR ADOPTION AS AMENDED OR SUBSTITUTED

6. Council on Science and Public Health Report 3 – National Drug Shortages-Update in lieu of Resolution 522 – Drug Shortages-Federal Agency Assessment of Reimbursement and Pricing Policy on Shortages
7. Council on Science and Public Health Report 5 – Guidelines for Mobile Medical Applications and Devices in lieu of Resolution 514 – Improving Familiarity With and Utilization of Mobile Medical Technology
8. Resolution 501 – Development of a Standardized Post-Conducted Electrical Exposure Medical Protocol and Educational Campaign
9. Resolution 502 – Breast Density Notification
10. Resolution 503 – Comprehensive Access to Safety Data from Clinical Trials
11. Resolution 506 – Salmonella Strategy
12. Resolution 508 – U.S. Preventive Services Task Force Reform
13. Resolution 509 – Impact of Pharmaceutical Advertising on Women's Health
14. Resolution 511 – Regulation of Electronic Nicotine Delivery Systems (ENDS)
    Resolution 518 – Treating E-Cigarettes as Tobacco Products
    Resolution 519 – Sales and Marketing of E-Cigarettes to Minors
    Resolution 521 – E-Cigarettes to be Treated the Same as Tobacco Products
15. Resolution 515 – Promotion of Methadone Education
16. Resolution 516 – Science, Technology, Engineering, and Mathematics (STEM) Undergraduate Education

17. Resolution 520 – Modification to the USP Chapter 797 Guidelines as Currently Written
18. Resolution 523 – President's Council on Science and Technology Report

RECOMMENDED FOR REFERRAL

19. Resolution 507 – Over the Counter (OTC) Insulin

RECOMMENDED FOR NOT ADOPTION

20. Resolution 504 – Arsenic in Food
21. Resolution 505 – Community Peanut Allergy Safety
22. Resolution 517 – Genetically Modified Organisms Labeling

RECOMMENDED FOR REAFFIRMATION IN LIEU OF

23. Resolution 510 – Labeling of Foods and Packaging Containing Engineered Nanoparticles

(1) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 1 - CSAPH SUNSET REVIEW OF 2004 HOUSE POLICIES

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that the recommendation in Council on Science and Public Health Report 1 be adopted and the remainder of the report filed.

HOD ACTION: Recommendation in Council on Science and Public Health Report 1 adopted and the remainder of the report filed.

Council on Science and Public Health Report 1 makes recommendations on the disposition of 2004 House policies assigned to the Council. The report recommends that the House of Delegates policies that are listed in the Appendix to the report be acted upon in the manner indicated in the Appendix and the remainder of the report be filed.

No extractions were requested from the Council's Sunset Report. Accordingly, your Reference Committee recommends adoption.

(2) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 2 - GENOMIC-BASED APPROACHES TO THE RISK ASSESSMENT, MANAGEMENT AND PREVENTION OF TYPE 2 DIABETES

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that the recommendation in Council on Science and Public Health Report 2 be adopted and the remainder of the report filed.

HOD ACTION: Recommendation in Council on Science and Public Health Report 2 adopted and the remainder of the report filed.

Council on Science and Public Health Report 2 reviews genomic-based strategies aimed at improving the clinical care of type 2 diabetes. The report recommends that our American Medical Association encourage continued research into the potential of genomic information to improve risk assessment, management and prevention of type 2 diabetes, and report back on important advances as appropriate.

Supportive testimony was offered on the Council's report, noting that type 2 diabetes is a complex disease with a growing public health burden and that innovative solutions are required to adequately address it. The Council noted that genomic approaches to the management and prevention of diabetes are promising, and that further research should

be encouraged. Your Reference Committee agrees and urges adoption of the report's recommendation.

(3) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 4 - BIOSIMILAR PRODUCT APPROVAL AND MARKETING

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that the recommendations in Council on Science and Public Health Report 4 be adopted and the remainder of the report filed.

(2) That Policy D-125.989, "Substitution of Biosimilar Medicines and Related Medical Products," be amended by addition and deletion to read as follows:
Our AMA urges that State Pharmacy Practice Acts and substitution practices for biosimilars in the outpatient arena: (1) ~~mirror the current practices for A-rated generic drugs by~~ preserve~~ing~~ physician autonomy ~~the right of physicians and other prescribers~~ to designate which biologic or biosimilar product is dispensed to their patients; (2) allow substitution when physicians expressly authorize substitution of an interchangeable product ~~or their consent is implied by remaining silent or expressing no preference regarding substitution of such products~~; (3) limits the authority of pharmacists to automatically substitute only those biosimilar products that are deemed interchangeable by the FDA. (Res. 918, I-08; Modified: CSAPH Rep. 1, I-11);

HOD ACTION: Recommendations in Council on Science and Public Health Report 4 adopted as amended and the remainder of the report filed.

Council on Science and Public Health Report 4 revisits the topic of biosimilars, studying emerging issues that are relevant for such products under the current abbreviated pathway for approval, and recommending changes to relevant AMA policy. The report recommends:
(1) That Policy H-125.980, "Abbreviated Pathway for Biosimilar Approval," be amended by addition and deletion to read as follows:
~~AMA policy is that pharmaceutical companies should be allowed to make biosimilar medications available to physicians and their patients in a reasonable period of time with a reasonably predictable pathway to bring them to market.~~ Our AMA supports ~~will advocate for appropriate~~ FDA ~~Guidance and~~ implementation of the Biologics Price ~~and~~ Competition and Innovation Act of 2009 in a manner that~~: 1) includes a straightforward regulatory process for an abbreviated approval pathway for biosimilars; 2~~1) places appropriate emphasis on ~~the~~ promoting patient access, protecti~~o~~ng ~~of~~ patient safety, and preserving market competition and innovation ~~in both the original branded products and~~

~~all biosimilar products that are brought to market~~; ~~and~~ ~~3~~2) includes planning by the FDA and the allocation of sufficient resources to ensure that physicians understand the distinctions between biosimilar products that are considered highly similar, and those that are deemed interchangeable. Focused educational activities must precede and accompany the entry of biosimilars into the U.S. market, both for physicians and patients; 3) includes compiling and maintaining an official compendium of biosimilar products, biologic reference products, and their related interchangeable biosimilars as they are developed and approved for marketing by the FDA.(Res. 220, A-09; Reaffirmation A-11; Modified: CSAPH Rep. 1, I-11);

(2) That Policy D-125.989, "Substitution of Biosimilar Medicines and Related Medical Products," be amended by addition and deletion to read as follows:
Our AMA urges that State Pharmacy Practice Acts and substitution practices for biosimilars in the outpatient arena: (1) ~~mirror the current practices for A-rated generic drugs by~~ preserve~~ing~~ physician autonomy ~~the right of physicians and other prescribers~~ to designate which biologic or biosimilar product is dispensed to their patients; (2) allow substitution only either when physicians expressly authorize substitution of an interchangeable product or their consent is implied by remaining silent or expressing no preference regarding substitution of such products; (3) limits the authority of pharmacists to automatically substitute only those biosimilar products that are deemed interchangeable by the FDA. (Res. 918, I-08; Modified: CSAPH Rep. 1, I-11);

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

(4) That Policy D-125.988, "Updating AMA Policy on Biosimilars," be rescinded.

Testimony was supportive of the Council's updated report on biosimilars, with many noting that biologics are complex therapeutics and regulation of them should take into account their unique properties. Some sentiment was expressed for a unique naming convention for biosimilars intended to enhance product identification and postmarketing surveillance, and for physician notification in the event that an interchangeable biosimilar is substituted at the level of the pharmacy. Considerable uncertainty exists about the need for, and potential impacts of, these specific actions on market development since there has been little development in the United States. Accordingly your Reference Committee is comfortable with the Council's analysis and adoption of the recommendations contained in Report 4.

(4) RESOLUTION 512 - RISK EVALUATION AND MITIGATION STRATEGIES (REMS) FOR METHADONE

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Resolution 512 be adopted.

HOD ACTION: Resolution 512 referred.

Resolution 512 asks that our American Medical Association (1) urge the US Food and Drug Administration to require an "individual" Risk Evaluation and Mitigation Strategy (REMS) for the clinical use of methadone in pain management; and (2) advocate that the manufacturer deemed responsible for developing a methadone-specific REMS consult experts in pain medicine in designing the program.

Testimony noted that a risk evaluation and mitigation strategy (REMS) currently exists for methadone as part of a broader REMS for so-called extended release and long-acting (ER/LA) opioid analgesic products, and that the number of unintentional overdoses and deaths attributable to the use of methadone as a pain reliever is disproportionate to the actual prescribing rate for methadone. The view was strongly expressed that methadone is a product with such unique pharmacokinetic and pharmacodynamic properties that it is more rational for safety reasons to establish a singular REMS strategy for methadone. While considerable effort has already been extended to developing and implementing the ER/LA opioid REMS program, your Reference Committee agrees that methadone's unique safety profile is reason to request that it be separated from other opioid analgesic products.

(5) RESOLUTION 513 - ANTIBIOTIC USE IN FOOD PRODUCING ANIMALS

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that Resolution 513 be adopted.

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that Policy H-440.895 be rescinded.

HOD ACTION: Resolution 513 adopted and Policy H-440.895 be rescinded.

Resolution 513 asks that our American Medical Association (1) support federal efforts to ban antibiotic use in food-producing animals for growth promotion purposes, including through regulatory and legislative measures; (2) support a strong federal requirement that antibiotic prescriptions for animals be overseen by a veterinarian knowledgeable of the place and intended use of these drugs, under a valid veterinarian-client-patient

relationship (VCPR); and (3) support efforts to expand FDA surveillance and data collection of antibiotic use in agriculture.

Limited testimony was offered in support of Resolution 513. This remains an important public health issue with a growing body of evidence that human health is harmed by the prophylactic off-label use of antibiotics in animals. Therefore, your Reference Committee recommends adoption. Since adoption of this resolution would create policy more stringent than H-440.895, your Reference Committee recommends rescinding that policy.

Policy to be rescinded:
H-440.895 Antimicrobial Use and Resistance
Our AMA is opposed to the use of antimicrobials at non-therapeutic levels in agriculture, or as pesticides or growth promoters, and urges that non-therapeutic use in animals of antimicrobials (that are also used in humans) should be terminated or phased out based on scientifically sound risk assessments. (Res. 508, A-01; Reaffirmed: CSAPH Rep. 1, A-11)

(6) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 3 - NATIONAL DRUG SHORTAGES-UPDATE
RESOLUTION 522 - DRUG SHORTAGES–FEDERAL AGENCY ASSESSMENT OF REIMBURSEMENT AND PRICING POLICY ON SHORTAGES

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that the recommendation in Council on Science and Public Health Report 3 be amended by addition on page 7, line 35 to read as follows:

7. Our AMA urges the development of a comprehensive independent report on the root causes of drug shortages. Such an analysis should consider federal actions, the number of manufacturers, economic factors, including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and pricing. In particular, further transparent analysis of economic drivers is warranted. The Centers for Medicare and Medicaid Services should review and evaluate its 2003 Medicare reimbursement formula of average sales price plus 6% for unintended consequences, including serving as a root cause of drug shortages. ~~The Council will monitor and evaluate the forthcoming report on drug shortages from the Government Accountability Office and report back on its findings~~. (Modify HOD Policy).

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that the recommendation in Council on Science and Public Health Report 3 be adopted as amended in lieu of Resolution 522 and the remainder of the report filed.

HOD ACTION: Recommendation in Council on Science and Public Health Report 3 adopted as amended in lieu of Resolution 522 and the remainder of the report filed.

Council on Science and Public Health Report 3 evaluates the findings of the 2014 Government Accountability Office (GAO) report on drug shortages and the current status of drug shortages in the United States, as well as other recent developments intended to prevent new drug shortages and resolve existing ones. The report recommends that Policy H-100.956 "National Drug Shortages" be amended by addition and deletion as follows:

1. That our AMA supports the recommendations of the 2010 Drug Shortage Summit convened by the American Society of Health System Pharmacists, American Society of Anesthesiologists, American Society of Clinical Oncology and the Institute for Safe Medication Practices and will work in a collaborative fashion with these and other stakeholders to implement these recommendations in an urgent fashion.
2. Our AMA supports requiring all manufacturers of Food and Drug Administration approved drugs and, including FDA approved drugs with recognized off-label uses, to give the agency advance notice (at least 6 months prior or otherwise as soon as practicable) of anticipated voluntary or involuntary, permanent or temporary, discontinuance of the manufacture or marketing of such a product.
3. Our AMA supports authorizing the Secretary of Health and Human Services to expedite facility inspections, and the review of manufacturing changes, drug applications and supplements that would help mitigate or prevent a drug shortage.
4. Our AMA supports the creation of a task force to enhance the HHS Secretary's response to preventing and mitigating drug shortages and to create a strategic plan to: (a) enhance interagency coordination; (b) address drug shortage possibilities when initiating regulatory actions (including the removal of unapproved drug products from the market); (c) improve FDA's ability to track and analyze drug shortage data in an effort to develop strategies to better prevent drug shortages (~~c~~d) provide further information on expedited solutions that have worked to prevent or mitigate drug shortages; (e) communicate with stakeholders; and (~~d~~f) consider the impact of drug shortages on research and clinical trials.
5. Our AMA will advocate that the U.S. Food and Drug Administration and/or Congress require drug manufacturers to establish a plan for continuity of supply of vital and life-sustaining medications and vaccines to avoid production shortages whenever possible. This plan should include establishing the necessary resiliency and redundancy in manufacturing capability to minimize disruptions of supplies in foreseeable circumstances including the possibility of a disaster affecting a plant.
6. The Council on Science and Public Health shall continue to evaluate the drug shortage issue and report back at least annually to the House of Delegates on progress made in addressing drug shortages.
7. Our AMA urges the development of a comprehensive independent report on the root causes of drug shortages. Such an analysis should consider federal actions, the number of manufacturers, economic factors, including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and

pricing. In particular, further transparent analysis of economic drivers is warranted. ~~The Council will monitor and evaluate the forthcoming report on drug shortages from the Government Accountability Office and report back on its findings~~.

8. Our AMA urges that procedures be put in place: (1) for the FDA to monitor the availability of Schedule II controlled substances; (2) for the FDA to identify the existence of a shortage that is caused or exacerbated by existing production quotas; and, (3) for expedited DEA review of requests to increase aggregate and individual production quotas for such substances.

9. Our AMA urges regulatory relief designed to improve the availability of prescription drugs by ensuring that such products are not removed from the market due to compliance issues unless such removal is clearly required for significant and obvious safety reasons.

10. Our AMA supports the view that wholesalers should routinely institute an allocation system that attempts to fairly distribute drugs in short supply based on remaining inventory and considering the customer's purchase history.

11~~0~~. Our AMA will collaborate with medical specialty partners in identifying and supporting legislative remedies to allow for more reasonable and sustainable payment rates for prescription drugs. (CSAPH Rep. 2, I-11; Modified: CSAPH Rep. 7, A-12; Modified: CSAPH Rep. 2, I-12; Modified: CSAPH Rep. 8, A-13; Modified in lieu of Res. 912, I-13.

Resolution 522 asks that our American Medical Association (1) request the Centers for Medicare & Medicaid Services review their 2003 Medicare reimbursement formula of average sales price plus 6% for the unintended consequences of affecting market availability, especially for childhood leukemia, intensive care and anesthesia injectable therapies; and (2) request CMS to review the 2003 Medicare reimbursement formula of average sales price plus 6% as a root cause for drug shortages for American patients, especially in face of the Government Accountability Office report of 2014 – Drug Shortages: Public Health Threat continues despite efforts to ensure product availability.

The Council was thanked for keeping the House informed about the ongoing nature of drug shortages in the United States. Testimony acknowledged the continuing burden that drug shortages place on physicians and their patients. Although the recent GAO report on drug shortages provided some economic analysis of the root causes of drug shortages, additional evaluation of economic drivers of drug shortages and renewed attention to the potential role of the CMS reimbursement formula as a potential root cause of drug shortages is warranted. The view also was expressed that the predominant cause of drug shortages is over-regulation by the FDA and "price fixing" based on implementation of the CMS reimbursement formula. The Council has not endorsed this view.

(7) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 5 - GUIDELINES FOR MOBILE MEDICAL APPLICATIONS AND DEVICES
RESOLUTION 514 - IMPROVING FAMILIARITY WITH AND UTILIZATION OF MOBILE MEDICAL TECHNOLOGY

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that the recommendations in Council on Science and Public Health Report 5 be amended by addition of a new Recommendation 3.

1. That our American Medical Association (AMA) monitor market developments in mobile health (mHealth), including the development and uptake of mHealth apps, in order to identify developing consensus that provides opportunities for AMA involvement. (Directive to Take Action)

2. That our AMA continue to engage with stakeholders to identify relevant guiding principles to promote a vibrant, useful and trustworthy mHealth market. (Directive to Take Action)

3. That our AMA make an effort to educate physicians on mHealth apps that can be used to facilitate patient communication, advice, and clinical decision support, as well as resources that can assist physicians in becoming familiar with mHealth apps that are clinically useful and evidence-based.

~~3~~4. That Policy D-480.975, "Guidelines for Mobile Medical Applications and Devices," be rescinded. (Rescind HOD Policy)

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that the recommendations in Council on Science and Public Health Report 5 be adopted as amended in lieu of Resolution 514 and the remainder of the report filed.

HOD ACTION: Recommendations in Council on Science and Public Health Report 5 adopted as amended in lieu of Resolution 514 and the remainder of the report filed.

Council on Science and Public Health Report 5 examines key trends and findings relevant to the developing field of mobile health (mHealth) apps, and how these realities

impact the feasibility of our AMA taking a leadership or convening role in this arena. The report recommends that (1) our (AMA) monitor market developments in mobile health, including the development and uptake of mHealth apps, in order to identify developing consensus that provides opportunities for AMA involvement; (2) our AMA continue to engage with stakeholders to identify relevant guiding principles to promote a vibrant, useful and trustworthy mHealth market; and (3) Policy D-480.975, "Guidelines for Mobile Medical Applications and Devices," be rescinded.

Resolution 514 asks that our American Medical Association (1) develop programming to educate physicians on how to use mobile applications for clinical decision-making support and for communication with patients, as well as how to advise patients to best use mobile technology; (2) work with other interested stakeholders, such as the innovators of existing apps and other medical societies, to develop or improve existing apps to deliver accurate medical information based on current medical guidelines; (3) educate physicians on discerning between useful, evidence-based apps and apps that are inaccurate; and (4) develop and maintain a list of "quality apps" that are evidence-based and user-friendly for provider use and for providers to recommend to their patients.

Testimony reflected the rapid development occurring in the field of mHealth around the use of mobile medical apps and the fact that an urgent need exists for a trusted source to provide guidance for physicians and their patients on mobile medical apps. The AMA was urged to step into the developing gap between the pace of mobile medical app development and marketing, and the need for evidence-based evaluation of usefulness. General support was offered for Resolves 1 and 3 in Resolution 514 and your Reference Committee has incorporated the concepts of these resolves as an amendment to the recommendations in the Council report. Your Reference Committee believes this approach still offers the necessary flexibility for our AMA to determine the best course of action to become more formally engaged in this field.

(8) RESOLUTION 501 - DEVELOPMENT OF A STANDARDIZED POST-CONDUCTED ELECTRICAL EXPOSURE MEDICAL PROTOCOL AND EDUCATIONAL CAMPAIGN

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that Policy H-145.977 be amended by addition and deletion to read as follows:

H-145.977 Use of ~~Tasers~~ Conducted Electrical Devices by Law Enforcement Agencies
Our AMA: (1) recommends that law enforcement departments and agencies should have in place specific guidelines, rigorous training, and an accountability system for the use of conducted electrical devices (CEDs) that is modeled after available national guidelines; (2) encourages additional independent research involving actual field deployment of CEDs to better understand the

risks and benefits under conditions of actual use. Federal, state, and local agencies should accurately report and analyze the parameters of CED use in field applications; and (3) policy is that law enforcement departments and agencies have a standardized ~~approach to~~ protocol developed with the input of the medical community for the ~~medical~~ evaluation, management and post-exposure monitoring of subjects exposed to CEDs (CSAPH Rep. 6, A-09)

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that amended Policy H-145.977 be adopted in lieu of Resolution 501.

HOD ACTION: Amended Policy H-145.977 adopted in lieu of Resolution 501.

Resolution 501 asks that our American Medical Association (1) encourage appropriate organizations and medical specialty societies to develop a standardized, post-exposure medical protocol for the use of conducted electrical devices (CEDs) using recent advances in the understanding of the risks associated with CEDs; and (2) support the incorporation of a standardized post-conducted electric device (CED)-exposure medical protocol into law enforcement procedures and training.

Testimony offered on Resolution 501 was mostly supportive, acknowledging that new data were available on the risks associated with the use of CEDs, and the need to develop standardized protocols for medical management and monitoring. Testimony also noted the need to ensure that CEDs are used appropriately by law enforcement personnel and that the use of CEDs does not present avoidable health risks to those on whom they are used. The Council on Science and Public Health reminded the Committee that it had developed a report and recommendations on CED use in 2009 that contains useful guidance. Policy adopted from that report already supports the medical evaluation and post-exposure monitoring that is called for in Resolve 2 of the resolution. Your Reference Committee recommends amending current policy to support the contemporary development of a standardized post-exposure medical protocol, based on input from the medical community, for individuals who have been exposed to CEDs.

(9) RESOLUTION 502 - BREAST DENSITY NOTIFICATION

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that Resolution 502 be amended by addition and deletion on line 31-34 to read as follows:

RESOLVED, That our American Medical Association supports the inclusion of breast tissue density information in the mammography report when appropriate

and education of patients about the clinical relevance of such information, but opposes state ~~the~~ requirements for mandatory notification of breast tissue density to patients ~~unless and until it is demonstrated that supplemental ancillary screening studies are cost-effective and clinically proven to improve patient care outcomes~~. (New HOD Policy)

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that Resolution 502 be adopted as amended.

HOD ACTION: Resolution 502 adopted as amended.

Resolution 502 asks that our American Medical Association oppose the mandatory notification of breast tissue density to patients unless and until it is demonstrated that supplemental ancillary screening studies are cost-effective and clinically proven to improve patient care outcomes.

Mostly supportive testimony was offered on Resolution 502. While some noted the value of fully informing patients about their health status and breast cancer risks, others cited the unclear evidence linking breast density to breast cancer risk. Concerns were aired about government intrusion into the practice of medicine, and that AMA policy on this topic is needed as more states consider breast density notification laws. Your Reference Committee recommends amendments to the resolution to support the inclusion of breast density information in the mammography report when appropriate and education of patients about the clinical relevance of such information. Your Reference Committee agrees that states should not mandate notification of patients about breast density.

(10) RESOLUTION 503 - COMPREHENSIVE ACCESS TO SAFETY DATA FROM CLINICAL TRIALS

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that Resolution 503 be amended by addition and deletion on page 2, lines 10-20 to read as follows:

RESOLVED, That our American Medical Association urge the ~~Federal~~ Food and Drug Administration to investigate and develop means by which ~~academic~~ scientific investigators can access original source safety data from industry-sponsored trials upon request (Directive to Take Action); and be it further

RESOLVED, That our AMA support the adoption of universal policy by medical journals requiring ~~principal~~ participating investigators to have

independent access to all study data from industry-sponsored trials. (New HOD Policy)

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that Resolution 503 be adopted as amended.

RECOMMENDATION C:

Mr. Speaker, your Reference Committee recommends that the title of Resolution 503 be changed to read as follows:

ACCESS TO CLINICAL TRIAL DATA

HOD ACTION: Resolution 503 adopted as amended with change in title.

Resolution 503 asks that our American Medical Association (1) urge the Federal Drug Administration to investigate and develop means by which academic investigators can access original source safety data from industry-sponsored trials upon request; and (2) support the adoption of universal policy by medical journals requiring principal investigators to have independent access to all study data from industry-sponsored trials.

Testimony was supportive of this resolution. The FDA noted that efforts to provide access to clinical trial data are currently underway and that industry also is voluntarily developing data access policies. Your Reference Committee also is aware that a number of medical journals have instituted data access policies. Your Reference Committee supports the concept that increased access to trial data by scientific investigators can enhance medical knowledge and benefit public health. Accordingly, adoption of this resolution with minor amendments is recommended. Additionally, a change in title is recommended since the resolution addresses data that is not just related to safety.

(11) RESOLUTION 506 - SALMONELLA STRATEGY

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Substitute Resolution 506 be adopted.

REDUCING SALMONELLA OUTBREAKS

RESOLVED, That our AMA support USDA and FDA efforts to improve standards for *Salmonella* testing and sampling in chicken slaughter facilities and other food processing plants to reduce human *Salmonella* infection. (New HOD Policy)

HOD ACTION: Substitute Resolution 506 adopted.

Resolution 506 asks that our American Medical Association (1) advocate for more stringent sampling and testing techniques; and (2) advocate for new testing standards at slaughter facilities and the development of standards relating to salmonella contamination in cut chicken parts.

Supportive testimony was offered for Resolution 506, citing recent outbreaks of Salmonella and the number of people affected. Your Reference Committee is aware that the USDA and the FDA are working to continually improve the guidelines for food processing facilities to reduce the chances of Salmonella contamination. Your Reference Committee believes that the adoption of a substitute resolution broadly supporting these efforts is in order rather than limiting the policy only to cut chicken parts.

(12) RESOLUTION 508 - US PREVENTIVE SERVICES TASK FORCE REFORM

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that Resolution 508 be amended by deletion of the second resolve.

~~RESOLVED, That our AMA reaffirm AMA Policy D-425.992, Recommendations by the USPSTF, which states: "Our AMA will expresses concern regarding recent recommendations by the United States Preventive Services Task Force (USPSTF) on screening mammography and prostate specific antigen (PSA) screening and the effects these USPSTF recommendations have on limiting access to preventive care for Americans and will encourage the USPSTF to implement procedures that allow for meaningful input on recommendation development from specialists and stakeholders in the topic area under study." (Reaffirm HOD Policy)~~

RECOMMENDATION B:
Mr. Speaker, your Reference Committee recommends that Resolution 508 be adopted as amended.

HOD ACTION: Resolution 508 adopted as amended.

Resolution 508 asks that our American Medical Association
(1) amend existing policy H-330.896 to read as follows:
Our AMA supports the following reforms to strengthen the Medicare program, to be implemented together or separately, and phased-in as appropriate: 1. Restructuring beneficiary cost-sharing so that patients have a single premium and deductible for all Medicare services, with means-tested subsidies and out-of-pocket spending limits that protect against catastrophic expenses. The cost-sharing structure should be developed

to provide incentives for appropriate utilization while discouraging unnecessary or inappropriate patterns of care. The use of preventive services ~~such as those recommended by the US Preventive Health Task Force~~ should also be encouraged. Simultaneously, policymakers will need to consider modifications to Medicare supplemental insurance (i.e., Medigap) benefit design standards to ensure that policies complement, rather than duplicate or undermine, Medicare's new cost-sharing structure. 2. Offering beneficiaries a choice of plans for which the federal government would contribute a standard amount toward the purchase of traditional fee-for-service Medicare or another health insurance plan approved by Medicare. All plans would be subject to the same fixed contribution amounts and regulatory requirements. Policies would need to be developed, and sufficient resources allocated, to ensure appropriate government standard-setting and regulatory oversight of plans. 3. Restructuring age-eligibility requirements and incentives to match the Social Security schedule of benefits (Modify Current HOD Policy); and

(2) reaffirm AMA Policy D-425.992, Recommendations by the USPSTF, which states: "Our AMA will express concern regarding recent recommendations by the United States Preventive Services Task Force (USPSTF) on screening mammography and prostate specific antigen (PSA) screening and the effects these USPSTF recommendations have on limiting access to preventive care for Americans and will encourage the USPSTF to implement procedures that allow for meaningful input on recommendation development from specialists and stakeholders in the topic area under study."

Extensive and mixed testimony was offered on Resolution 508. Many oppose the USPSTF's recent recommendations on mammography and prostate specific antigen (PSA) screening, especially noting that the PSA recommendation does not adequately apply to all races and ethnicities. Others note that the group does important work for primary care physicians, many of whom rely on the Task Force to provide unbiased recommendations based on the latest high-quality evidence. Substantial debate centered on the Task Force's process for soliciting input from the public, with many believing that medical specialties should be more involved. However, others noted the many opportunities for specialties to weigh in during the recommendation development process. Sponsors of the resolution are concerned that the reference to USPSTF recommendations in AMA policy H-330.896 implies endorsement of the recommendations. Your Reference Committee understands such concern, and recommends adoption of the first resolve. Regarding the second resolve, the directive has already been implemented by direct communication with the Task Force, and reaffirmation would not result in any further action. It therefore recommends deletion of the second resolve.

(13) RESOLUTION 509 - IMPACT OF PHARMACEUTICAL ADVERTISING ON WOMEN'S HEALTH

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that Resolution 509 be <u>amended by addition and deletion on page 1, lines 19-24</u> to read as follows:

RESOLVED, That our American Medical Association ~~collaborate with~~ urge the US Food and Drug Administration (FDA) to assure that all direct-to-consumer advertising of pharmaceuticals include~~s~~ information regarding differing effects and risks between the sexes (Directive to Take Action); and be it further

RESOLVED, That our AMA ~~collaborate with~~ urge the FDA to assure that advertising of pharmaceuticals to health care professionals include~~s~~ specifics outlining whether testing of drugs prescribed to both sexes has included sufficient numbers of women to assure safe use in this population and whether such testing has identified needs to modify dosages based on sex. (Directive to Take Action)

RECOMMENDATION B:
Mr. Speaker, your Reference Committee recommends that Resolution 509 be adopted as amended.

HOD ACTION: Resolution 509 adopted as amended.

Resolution 509 asks that our American Medical Association (1) collaborate with the US Food and Drug Administration (FDA) to assure that all direct-to-consumer advertising of pharmaceuticals includes information regarding differing effects and risks between the sexes; and (2) collaborate with the FDA to assure that advertising of pharmaceuticals to health care professionals includes specifics outlining whether testing of drugs prescribed to both sexes has included sufficient numbers of women to assure safe use in this population and whether such testing has identified needs to modify dosages based on sex.

Testimony on Resolution 509 was mostly supportive, citing the historic lack of female representation in clinical trials and the resulting differences that sometimes occur in drug metabolism and response among women and men. Your Reference Committee agrees with the intent of this resolution, but notes that no authority exists by which our AMA can "collaborate with" the FDA. It therefore recommends amendments to urge the FDA to assure that relevant sex difference data are available in direct-to-consumer advertisements for the benefit of both patients and physicians.

(14) RESOLUTION 511 - REGULATION OF ELECTRONIC NICOTINE DELIVERY SYSTEMS
RESOLUTION 518 - TREATING E-CIGARETTES AS TOBACCO PRODUCTS
RESOLUTION 519 - SALES AND MARKETING OF E-CIGARETTES TO MINORS
RESOLUTION 521 - E-CIGARETTES TO BE TREATED THE SAME AS TOBACCO PRODUCTS

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that Policy H-495.973 be amended by addition and deletion to read as follows:

H-495.973 FDA to Extend Regulatory Jurisdiction Over All Non-Pharmaceutical Nicotine and Tobacco Products
Our AMA ~~will urge~~ supports: (1) the U.S. Food and Drug Administration's (FDA) proposed rule ~~to immediately~~ that would implement ~~the~~ its deeming authority ~~written into the FDA tobacco law to~~ allowing the agency to extend FDA regulation of tobacco products to pipes, cigars, hookahs, e-cigarettes and all other non-pharmaceutical tobacco/nicotine products not currently covered by the FDA tobacco law~~.~~; (2) legislation and/or regulation addressing the minimum purchase age, locations of permissible use, the use of secure, child- and tamper-proof packaging and design, advertising and promotion activities, and sponsorship of e-cigarettes and all other non-pharmaceutical tobacco/nicotine products; (3) transparency and disclosure concerning the design, content of, and emission from e-cigarettes and all other non-pharmaceutical tobacco/nicotine products; (4) restrictions on the use of characterizing flavors that may enhance the appeal of such products to minors, and the development of strategies to prevent marketing to, and use of, e-cigarettes and all other non-pharmaceutical tobacco/nicotine products by minors; (5) the prohibition of claims of reduced risk and/or the marketing of e-cigarettes as tobacco cessation tools until such time that credible evidence is developed that supports such claims.

RECOMMMENDATION B:
Mr. Speaker, your Reference Committee recommends that amended Policy H-495.973 be adopted in lieu of Resolutions 511, 518, 519, and 521.

HOD ACTION: Amended Policy H-495.973 adopted in lieu of Resolutions 511, 518, 519, and 521.

Resolution 511 asks that our American Medical Association (1) support labeling and regulating Electronic Nicotine Delivery Systems (ENDS) as tobacco products and drug delivery devices; (2) support legislation that addresses the minimum purchasing age, locations of permissible use, advertising, promotion, and sponsorship of ENDS in a manner similar to those of tobacco products; (3) support transparency and disclosure concerning the design, content and emissions of ENDS; (4) support secure, child-proof, tamper-proof packaging and design of ENDS; (5) support enhanced labeling that warns of the potential consequences of ENDS use, restriction of ENDS marketing as tobacco

cessation tools, and restriction of the use of characterizing flavors in ENDS; and (6) support basic, clinical, and epidemiological research concerning ENDS.

Resolution 518 asks that our American Medical Association support the concept that e-cigarettes be considered tobacco products with all of the legal and policy restrictions with smoking in post-acute and long-term care facilities.

Resolution 519 asks that our American Medical Association (1) oppose the marketing, sales, and use of e-cigarettes and other nicotine delivery products to minors; and (2) work with federal and state lawmakers and officials to develop strategies to prevent marketing, sales, and use of e-cigarettes and other nicotine delivery products to minors.

Resolution 521 asks that our American Medical Association seek federal legislation that would place “e-cigarettes” and all nicotine delivery devices under the purview of the US Food and Drug Administration.

Testimony noted the recent proposed rule by the U.S. Food and Drug Administration that would extend the agency’s tobacco authority to cover additional tobacco products and therefore already addresses some of the requests in these resolutions. Products that would be “deemed” to be subject to FDA regulation are those that meet the statutory definition of a tobacco product, including currently unregulated marketed products such as electronic cigarettes (e-cigarettes).

Consistent with currently regulated tobacco products, under the proposed rule, makers of e-cigarettes would, among other requirements, register with the FDA and report product and ingredient listings; only market new tobacco products after FDA review; only make direct and implied claims of reduced risk if the FDA confirms that scientific evidence supports the claim and that marketing the product will benefit public health as a whole; and not distribute free samples. In addition, under the proposed rule, the following provisions would apply to newly “deemed” tobacco products: minimum age and identification restrictions to prevent sales to underage youth; requirements to include health warnings; and prohibition of vending machine sales, unless in a facility that never admits youth. Emphasis was placed on the need to strongly address issues related to the marketing of these products to, and uptake by, minors.

Testimony critical of the proposed rule contended that the FDA did not go far enough, particularly with respect to the use of flavorings, which may enhance appeal of e-cigarettes among youth. Preliminary evidence also suggests that the use of e-cigarettes may increase later adoption of other traditional tobacco products and may have other hazards associated with their use. The Council on Science and Public Health also noted that it plans to develop a report on e-cigarettes and their public health implications for I-14. In the meantime, your Reference Committee believes that current policy should be amended to provide a framework for AMA comments on the FDA’s proposed rule and for addressing certain outstanding (e.g., two year window for enforcement) and evolving issues (e.g., clarity of terminology, serious adverse events) with e-cigarettes.

(15) RESOLUTION 515 - PROMOTION OF METHADONE EDUCATION

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Substitute Resolution 515 be adopted.

EDUCATION TO PROMOTE RESPONSIBLE USE OF METHADONE FOR PAIN MANAGEMENT

RESOLVED, That our American Medical Association, in collaboration with Federation partners, collate and disseminate available educational and training resources on the use of methadone for pain management. (Directive to Take Action)

HOD ACTION: Substitute Resolution 515 adopted.

Resolution 515 asks that our American Medical Association (1) support the creation and distribution of specific training tools regarding the use of methadone and all extended-release opioids in chronic pain patients. These may include webinars, printed training materials or seminars among other choices; (2) make efforts to spread this information to all providers who would potentially treat chronic pain patients; and (3) would provide this training material and/or process by June 2015.

Testimony noted that a need exists to better educate some practitioners on the use of methadone. Methadone can be useful in the management of cancer pain, in palliative care, newborns experiencing neonatal abstinence syndrome, and in certain patients with chronic pain syndromes. The number of unintentional overdoses and deaths attributable to the use of methadone as a pain reliever is disproportionate to the actual prescribing rate for methadone. The view was strongly expressed that methadone is a product with unique pharmacokinetic and pharmacodynamic properties and focused education is necessary to allow safe use of this analgesic. A number of educational resources already exist on methadone, including modules developed as part of the extended release/long acting (ER/LA) opioid risk evaluation and mitigation strategy (REMS). Because of methadone's unique safety profile, specific training materials and opportunities are advisable. However, your Reference Committee believes a more expedient approach is to have our AMA, in cooperation with Federation partners, collate and disseminate available educational materials addressing the appropriate clinical use of methadone for pain management.

(16) RESOLUTION 516 – SCIENCE, TECHNOLOGY, ENGINEERING, AND MATHEMATICS (STEM) UNDERGRADUATE EDUCATION

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that Resolution 516 be amended by addition and deletion on page 2, lines 4-8 to read as follows:

RESOLVED: That our American Medical Association amend Policy H-170.985 by addition and deletion to read as follows:
H-170.985 Science, Technology, Engineering and Mathematics Education
~~The~~ Our AMA (1) ~~supports~~ is committed to working with other concerned organizations and agencies to ~~identify ways to~~ improve science, technology, engineering and mathematics (STEM) education and ~~science~~ ~~STEM~~ literacy in the nation, and to increase interest in STEM ~~science and education~~ on the part of the nation's youth, particularly underrepresented minorities. (Modify HOD Policy)

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that Resolution 516 be adopted as amended.

HOD ACTION: Resolution 516 adopted as amended.

Resolution 516 asks that our American Medical Association amend Policy H-170.985 by addition and deletion to read as follows:
H-170.985 Science Education
The AMA (1) ~~supports~~ is committed to working with other concerned organizations and agencies to ~~identify ways to~~ improve science, technology, engineering and mathematics (STEM) education and ~~science~~ STEM literacy in the nation, and to increase interest in STEM ~~science and~~ education on the part of the nation's youth.

Broad support was offered for this resolution, stressing the importance of preparing the nation’s youth for careers in the science, technology, engineering and math fields. Your Reference Committee recommends a minor amendment by deletion for grammatical purposes, but otherwise recommends adoption. Your Reference Committee appreciates the suggested amendment to include mention of minority youth by the Minority Affairs Section, but does not believe that it is necessary since the amended policy refers to all of the nation’s youth.

(17) RESOLUTION 520 - MODIFICATION TO THE USP CHAPTER 797 GUIDELINES AS CURRENTLY WRITTEN

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Substitute Resolution 520 be adopted.

~~REVISIONS TO THE IMMEDIATE USE EXCEPTION IN USP GENERAL CHAPTER <797>~~

~~RESOLVED, That our American Medical Association encourage all interested parties to review and comment on draft revisions to USP General Chapter <797>–*Pharmaceutical Compounding–Sterile Preparations*, with special attention to the "immediate use" exception, in light of recent reports of enforcement actions taken by The Joint Commission.~~

RESOLVED, That our American Medical Association inform physicians on the far-reaching effects of the immediate-use exception to practice and patient safety (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage and facilitate as a convener for all state, medical school, and specialty organization delegates to the United States Pharmacopeial Convention to protest the "immediate-use" exception to the USP Chapter 797 guidelines as currently written, including the "one-hour-rule," and seek reasonable accommodation and modification of Chapter 797 guidelines with interested stakeholders (Directive to Take Action); and be it further

RESOLVED, That our AMA encourage and facilitate as a convener for all state, medical school, and specialty organization delegates to the United States Pharmacopeial Convention to protest the USP Chapter 797 guidelines as currently written, including the prohibition to enter a container no more than twice, and seek reasonable accommodation and modification of Chapter 797 guidelines with interested stakeholders. (Directive to Take Action)

RESOLVED, That our AMA urge The Joint Commission and other deeming organizations to suspend the enforcement of the "immediate-use" exception to USP Chapter 797 as currently written, including the "one-hour-rule" until the reconvening of the USP in June 2015.

RESOLVED, That our AMA urge the USP to employ evidence-based methods to survey current medical practice as it relates to USP Chapter 797 guidelines.

HOD ACTION: Resolution 520 adopted as amended..

Resolution 520 asks that our American Medical Association (1) inform physicians on the far-reaching effects of the immediate-use exception to practice and patient safety; (2) encourage and facilitate as a convener for all state, medical school, and specialty organization delegates to the United States Pharmacopeial Convention to protest the "immediate-use" exception to the USP Chapter 797 guidelines as currently written, including the "one-hour-rule," and seek reasonable accommodation and modification of Chapter 797 guidelines with interested stakeholders; and (3) encourage and facilitate as a convener for all state, medical school, and specialty organization delegates to the United States Pharmacopeial Convention to protest the USP Chapter 797 guidelines as currently written, including the prohibition to enter a container no more than twice, and seek reasonable accommodation and modification of Chapter 797 guidelines with interested stakeholders.

Testimony reflected concerns about the potential impacts on clinical care of certain standards contained in USP General Chapter <797> *Pharmaceutical Compounding−Sterile Preparations,* specifically under the category pertaining to "immediate use" compounded sterile products (CSP). Recently The Joint Commission has been interpreting certain traditional practices involving admixtures in the hospital setting as violating USP <797>. Standards in question relate to the recommended time frame for administration of an immediate use CSP, and limitation on the number of times a container can be entered during the compounding process. Testimony noted that the immediate use provision is intended only for those situations where immediate patient administration of a CSP is needed, and that the standards are intended to ensure patient safety and reduce the risk of patient harm. Those who expressed concerns about the clinical ramifications of enforcement of the "immediate use" offered assurances that they also were motivated by the best interests of the patient. General Chapter <797> is currently under revision by the Compounding Expert Committee which also created an Expert Panel in April 2013 to provide additional expertise in sterile compounding, including members who are infection control specialists and microbiologists. Once the revisions are finalized, General Chapter <797> will be posted for a 90 day public review and comment period in the Pharmacopeial Forum. All stakeholders are invited to participate in this standard setting process by providing input and comment during this 90 day period. Given these realities, no need appears to exist for our AMA to serve as a convening body to urge revision to the "immediate use" provisions in the existing chapter.

(18) RESOLUTION 523 - PRESIDENT'S COUNCIL ON SCIENCE AND TECHNOLOGY REPORT

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that Resolution 523 be amended by addition and deletion on lines 13-14 to read as follows:

RESOLVED, That our American Medical Association analyze the President's Council on Science and Technology Report ~~of May 29~~ entitled "Better Health Care and Lower Costs: Accelerating Improvement through Systems Engineering" and respond as appropriate ~~provide recommendations as to its applicability to health care delivery~~. (Directive to Take Action)

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that Resolution 523 be adopted as amended.

HOD ACTION: Resolution 523 adopted as amended.

Resolution 523 asks that our American Medical Association analyze the President's Council on Science and Technology Report of May 29 and provide recommendations as to its applicability to health care delivery.

Limited but supportive testimony urged that our AMA review the President's Council on Science and Technology's recently released report on systems engineering approaches to health care. Your Reference Committee agrees that this would be a worthwhile endeavor for our AMA, and offers minor amendments to specify the name of the report and to allow our AMA staff to respond to the report's recommendations in a manner that would best suit its members.

(19) RESOLUTION 507 – OVER THE COUNTER (OTC) INSULIN

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Resolution 507 be referred.

HOD ACTION: Resolution 507 referred.

Resolution 507 asks that our American Medical Association seek federal regulation or legislation requiring insulin be available by prescription and to encourage individual states to seek regulations or legislation requiring prescriptions for insulin.

Testimony reflected concerns about the availability of several types of insulin preparations without the need for a prescription, and the possibility that patients obtaining this type of insulin may be doing so without consulting their physicians or without undergoing adequate medical evaluation. Concerns also were raised that individuals in certain occupations where a diagnosis of insulin dependent diabetes may preclude their employment (e.g., long haul truck drivers) might engage in self-treatment; in such cases, the health and welfare of the public may be threatened. However, no evidence was provided that such behaviors exist. Additionally, the impact of such a decision on patient access for those needing insulin on an emergency basis or who are unable to afford prescription insulin also is unknown. Your Reference Committee believes that more information is needed to make an informed decision about this resolution, and therefore recommends referral so that it can be sufficiently studied.

(20) RESOLUTION 504 - ARSENIC IN FOOD

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Resolution 504 not be adopted.

HOD ACTION: Resolution 504 not adopted.

Resolution 504 asks that our American Medical Association (1) endorse the establishment of guidelines for minimally acceptable levels of arsenic content in food; and (2) work with the United States Office of Management and Budget to develop, approve and disseminate these official guidelines for minimally acceptable levels of arsenic content in food under the laws of the US government.

Testimony noted that heavy metal contamination remains a relevant topic specifically with respect to the developing central nervous system and is of general interest under the topic of environmental contaminants. Regulatory challenges exist in establishing minimally acceptable levels for arsenic concentrations in food rather than a “minimal safe daily intake” based on various patterns of food intake. Some skepticism was expressed regarding whether this resolution was needed given that FDA has a long standing program of testing arsenic in a variety of foods. Additionally the agency is working on a draft risk assessment on arsenic in rice that it expects to release sometime this year and guidelines for arsenic levels in juices have already been established. Testimony also noted that it is the FDA, not the Office of Management and Budget, that oversees guidelines for levels of arsenic in food. Your Reference Committee therefore believes that this issue is not an urgent public health issue and recommends that Resolution 504 not be adopted.

(21) RESOLUTION 505 - COMMUNITY PEANUT ALLERGY SAFETY

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Resolution 505 not be adopted.

HOD ACTION: Resolution 505 not adopted.

Resolution 505 asks that our American Medical Association support that a) all food products and other items that may be consumed by humans be adequately labeled for 100% of all contents; b) wherever possible, especially airplanes, such peanut containing products will no longer be served; and c) adequate emergency equipment and expertise be available if needed.

Mixed testimony was offered on Resolution 505. It was noted that FDA regulations already require that packaged food containing peanuts be labeled as such, and that our AMA already has policy supporting the availability of emergency equipment and expertise on airplanes to handle allergic reactions. Your Reference Committee is aware that airlines have explored options for making flights peanut-free, but have concluded that it is impossible to guarantee a peanut-free flight because even if they do not serve peanuts, they cannot control what types of foods passengers bring onto planes. Airline policies generally encourage those with peanut allergies to contact their physician before airplane travel and carry appropriate medications with them. Your Reference Committee believes that current FDA regulations and our AMA's current policy sufficiently address the tasks of the resolution, and therefore recommends that it not be adopted.

(22) RESOLUTION 517 - GENETICALLY MODIFIED ORGANISMS LABELING

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Resolution 517 not be adopted.

HOD ACTION: Resolution 517 not adopted.

Resolution 517 asks that our American Medical Association (1) ask the World Health Organization to review its current support of genetically modified organisms (GMOs), specifically reviewing any potential conflicts of interest in the current research and the lack of human research, which leaves unanswered questions regarding safety; and (2) pursue and endorse a national law requiring the clear labeling of all genetically modified organisms (GMOs) or foods containing genetically modified ingredients.

Mixed testimony was offered on Resolution 519. The sponsors of the resolution believe that the public has a right to be informed about whether foods contain bioengineered ingredients. Testimony also noted that the FDA's science-based labeling policy states that labels need only list information about bioengineered ingredients if the food is significantly different from its non-bioengineered counterpart or if the food's nutritional profile has changed. The Council on Science and Public Health studied the issue of bioengineered foods two years ago, and concluded that thorough pre-market safety assessment and the FDA's labeling policy are effective in ensuring the safety of bioengineered foods. No new evidence has been published since the Council's report that suggests contrary findings. Your Reference Committee therefore recommends that the resolution not be adopted.

(23) RESOLUTION 510 - LABELING OF PACKAGING AND FOODS CONTAINING ENGINEERED NANOPARTICLES

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Policy H-480.949 be reaffirmed in lieu of Resolution 510.

HOD ACTION: Policy H-480.949 reaffirmed in lieu of Resolution 510.

Resolution 510 asks that our American Medical Association endorse labeling of foods and packaging containing engineered nanoparticles including nanoparticle specifications, as reasonable, to allow public health monitoring.

Limited but mixed testimony was offered on Resolution 510. Nearly all testimony supported the concept that nanotechnology is somewhat new and requires ongoing study and evaluation to determine whether it could be harmful to human health. The FDA's regulatory approach for foods containing nanoparticles is one of industry responsibility, i.e., the FDA considers industry responsible for ensuring that its products meet all applicable legal requirements, including standards for safety, regardless of the emerging nature of a technology involved in product manufacturing. The Council on Science and Public Health studied the topic of nanotechnology safety just last year, and concluded that studies have not yet determined what the effects of real-world nanotechnology exposure are, and that further study is needed. The Council also testified that in light of the uncertain health effects, it supports labeling of foods and food packaging containing nanotechnology. However, your Reference Committee believes that in the absence of data indicating any harmful effects of real-world nanotechnology exposure, it is not appropriate for labeling to be mandated. Instead, it supports further research and recommends reaffirmation of current policy.

Policy recommended for reaffirmation:
H-480.949 Nanotechnology, Safety and Regulation
Our AMA: (1) recognizes the benefits and potential risks of nanotechnology; (2) supports responsible regulation of nanomaterial products and applications to protect the public's health and the environment; and (3) encourages continued study on the health and environmental effects of exposure to nanomaterials. (CSAPH Rep. 2, A-13)

Mr. Speaker, this concludes the report of Reference Committee E. I would like to thank Peter N. Bretan, Jr., MD, Thomas H. Hicks, MD, Brent Mohr, MD, Barry Wall, MD, Gerald A. Wilson, MD, Theodore Zanker, MD, and all those who testified before the Committee.

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