In keeping with Resolution 601 (A-96), the Reference Committee recommends the following consent calendar for acceptance:

RECOMMENDED FOR ADOPTION

6. Resolution 510 – Skin Cancer Prevention Education in Communities of Color
7. Resolution 512 – Access to and Licensure of Essential Medicines

RECOMMENDED FOR ADOPTION AS AMENDED OR SUBSTITUTED

8. Board of Trustees Report 11 – Methadone Clinics and Prescription Monitoring Programs
9. Resolution 502 – The Use of Atypical Antipsychotic Medication in Pediatric Patients
10. Resolution 503 – Insufficient Sleep in Adolescents
11. Resolution 504 – Safety and Labeling of Pharmaceuticals and Nutraceuticals
12. Resolution 505 – The Dry Antibiotic Pipeline and the 10 by ’20 Initiative
13. Resolution 508 – Prescription Leaflets
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PLEASE NOTE:

- AMA Policy H-440.979 was reaffirmed in lieu of Resolution 511.
- AMA Policies H-120.958 and H-100.964 were reaffirmed in lieu of Resolution 513.
- AMA Policy H-100.968 was reaffirmed in lieu of Resolution 517.
(1) COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT

3 - UPDATE ON THE FOOD AND DRUG ADMINISTRATION’S (FDA) EFFORTS TO IMPROVE FOOD SAFETY

RESOLUTION 518 – PUBLIC SAFETY RELATED TO THE FOOD INDUSTRY

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that the Recommendations in Council on Science and Public Health Report 3 be adopted in lieu of Resolution 518 and the remainder of the report be filed.


Report 3 of the Council on Science and Public Health responds to the final request of Resolution 520 (A-09) by providing background information on the 2007 Food Safety Plan and the 2009 President’s Food Safety Working Group, and describing the new 2010 initiative known as the “Transforming Food Safety Initiative,” which is intended to improve the safety of the country’s food supply. This report recommends that our AMA:

(1) support regulatory and legislative changes that will empower the Food and Drug Administration (FDA) to implement its “Transforming Food Safety Initiative” built upon the three core principles of prioritizing prevention, strengthening surveillance and enforcement, and improving response and recovery; (2) monitor the implementation of the “Transforming Food Safety Initiative,” and provide feedback to the FDA as necessary; (3) urge physicians to remain informed on the diagnosis and management of foodborne illnesses and to report suspected cases of foodborne illnesses to their local public health authority; and (4) rescind Policy D-440.944[2].

Resolution 518 asks that our AMA support pending bipartisan federal legislation such as the Food Safety Enhancement Act of 2009 and/or related bills to improve the Food and Drug Administration’s supervision of the nation’s food supply.

The Council summarized the objectives and recommendations in Report 3, and the sponsor of Resolution 518 was amenable to adoption of the report’s recommendations in lieu of the resolution. No other testimony was offered on these items.
COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT
4 - GENOMIC-BASED PERSONALIZED MEDICINE

RECOMMENDATION:

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


Report 4 of the Council on Science and Public Health reviews the current status of genomic-based PM and challenges to implementing it, and briefly summarizes the activities of key federal agencies, professional organizations, coalitions, and health systems that are working to further the integration of genomic-based technologies into routine care. This report recommends that our AMA: (1) reaffirm Directives D-460.976, “Genomic and Molecular-based Personalized Health Care,” and D-480.987, “Direct-to-Consumer Marketing and Availability of Genetic Testing;” (2) acknowledge the increasingly important role of genomic-based personalized medicine applications in the delivery of care, and will continue to assist in informing physicians about relevant personalized medicine issues; (3) continue to develop educational resources and point-of-care tools to assist in the clinical implementation of genomic-based personalized medicine applications, and will continue to explore external collaborations and additional funding sources for such projects; and (4) continue to represent physicians’ voices and interests in national policy discussions of issues pertaining to the clinical implementation of genomic-based personalized medicine, such as genetic test regulation, clinical validity and utility evidence development, insurance coverage of genetic services, direct-to-consumer genetic testing, and privacy of genetic information.

Your Reference Committee heard fully supportive testimony for this report. A representative from the National Institutes of Health noted that there are federal agencies in addition to those profiled in the report that are involved in personalized medicine activities, and pointed out the need to integrate genomics into health information technology systems.
HOD ACTION: Council on Science and Public Health
Report 5 adopted and the remainder of the report filed.


This report follows a previous report by the Council on neuropathic pain which focused on pharmacological management. It addresses recent findings on the pathogenesis of persistent pain which may develop following neural injury or the inadequate management of ongoing normal pain responses following tissue injury or inflammation. This report also addresses the non-pharmacologic management of pain in such patients. Limited but complimentary testimony was offered for this report.

COUNCIL ON SCIENCE AND PUBLIC HEALTH REPORT 8 - THE EVOLVING CULTURE OF DRUG SAFETY IN THE UNITED STATES: RISK EVALUATION AND MITIGATION STRATEGIES (REMS)

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that the Recommendations in Council on Science and Public Health Report 8 be adopted and the remainder of the report be filed.

HOD ACTION: Council on Science and Public Health
Report 8 adopted and the remainder of the report filed.

Council on Science and Public Health Report 8 briefly reviews some important milestones and developments in the evolving nature of drug safety activities among the Food and Drug Administration (FDA), the industry it regulates, and physician prescribers. The report recommends that: (1) the Food and Drug Administration (FDA) issue a final industry guidance on Risk Evaluation and Mitigation Strategies (REMS) with provisions that: (a) require sponsors to consult with impacted physician groups and other key stakeholders early in the process when developing REMS with elements to assure safe use (ETASU); (b) establish a process to allow for physician feedback regarding emerging issues with REMS requirements; (c) clearly specify that sponsors must assess the impact of ETASU on patient access and clinical practice, particularly in underserved areas or for patients with serious and life threatening conditions, and to make such assessments publicly available; and (d) conduct a long-term assessment of the prescribing patterns of drugs with REMS requirements; (2) the FDA ensure appropriate Advisory Committee review of proposed REMS with ETASU before they are finalized as part of the premarket review of New Drug Applications, and that the Drug Safety and Risk Management Advisory Committee fulfills this obligation for drugs that are already on the market and subject to REMS because of new safety information; (3) to the extent
practicable, a process is established whereby the FDA and sponsors work toward standardizing procedures for certification and enrollment in REMS programs, and the common definitions and procedures for centralizing and standardizing REMS that rely on ETASU are developed; and (4) REMS-related documents intended for patients (e.g., Medication Guides, acknowledgment/consent forms) be tested for comprehension and be provided at the appropriate patient literacy level in a culturally competent manner.

Council on Science and Public Health Report 8 is intended as a primer on evolving risk management strategies for prescription drugs with a focus on so-called risk evaluation and mitigation strategies (REMS) that employ elements of restricted distribution. The AMA previously sent a letter to FDA Commissioner Margaret Hamburg, MD, on this topic and has previously testified or commented numerous times on the FDA’s approach to risk management for prescription drugs. Recommendation #4 which addresses the need for appropriate literacy of patient materials was especially noted. Some sentiment was expressed for adding a specific comment on the emerging class of REMS for certain Schedule II opioid medications, and the need to expand that proposal to include all opioid medications. Opinions on the desirable features of an opioid REMS are widely divergent among Federation members, and a revised proposal on opioid REMS is scheduled for discussion at a July 22-23 joint meeting of the FDA’s Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee Meeting. Because the Council report does not specifically evaluate issues associated with an opioid REMS and a revised proposal is forthcoming from the Industry Working Group, your Reference Committee believes that additional recommendations on this issue are not appropriate for this report. An editorial change was suggested for page 8, line 6 of the report to change the word “urge” to recommend” and this will be accomplished.

(5) RESOLUTION 506 - ENCOURAGE A REVIEW OF THE EVIDENCE FOR ROUTINE HIV TESTING BY THE US PREVENTIVE SERVICES TASK FORCE

RECOMMENDATION:

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

HOD ACTION: Resolution 506 adopted.

Resolution 506 asks that our AMA (1) encourage a review of the evidence for routine HIV testing by the US Preventive Services Task Force; and (2) support coverage of an appropriate reimbursement for routine HIV testing by all public and private payers.

Your Reference Committee heard nearly unanimous testimony in support of Resolution 506. In the United States, nearly one million people are infected with HIV, but an estimated 25 percent are not aware of their status. Early diagnosis of HIV may limit transmission rates and enable earlier treatment, however, because testing coverage is not guaranteed this creates a hindrance to detection. The U.S. Preventive Services Task Force (USPSTF) currently applies a “C” rating to routine HIV screening (a “C” rating means that the USPSTF makes no recommendation for or against the routine screening for HIV, adolescents and adults who are not at increased risk for HIV
infection). Testimony strongly urged that the evidence applied to routine HIV screening needs to be reviewed again. Because a rating of C is currently applied, coverage is lacking for HIV tests (coverage typically requires an A or B rating). Testimony noted that the USPSTF is planning to review the C rating again, but there was no information provided as to a possible timeline for this review.

(6) RESOLUTION 510 - SKIN CANCER PREVENTION EDUCATION IN COMMUNITIES OF COLOR

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Resolution 510 be adopted.

HOD ACTION: Resolution 510 adopted.

Resolution 510 asks that our AMA: (1) support and encourage prevention efforts to increase awareness of skin cancer risks and sun-protective behavior in communities of color; and (2) work with the American Academy of Dermatology, National Medical Association and National Hispanic Medical Association and public health organizations to promote education on the importance of skin cancer screening and skin cancer screening in patients of color.

Your Reference Committee heard testimony in support of this resolution. Several individuals testified believed there was not enough awareness of skin cancer risks in communities of color. It was noted that some physicians also are concerned with the lack of research into vitamin D deficiency in such individuals.

(7) RESOLUTION 512 - ACCESS TO AND LICENSURE OF ESSENTIAL MEDICINES

RECOMMENDATION:

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

HOD ACTION: Resolution 512 adopted.

Resolution 512 asks that our AMA amend Policy H-100.963 by insertion and deletion as follows: Our AMA: (1) supports universities engaging nontraditional partners, including public-private partnerships, grant-making organizations, nonprofits, and developing-world research institutions, in order to create new opportunities for neglected disease drug development; and (2) supports the protection of fair access to essential medicines in developing countries; and (3) supports policies that encourage institutions receiving publicly-funded research grants that result in patentable biomedical technologies to adopt transparent licensing provisions that provide equitable generic access to essential medicines for the developing world.

Your Reference Committee heard limited but supportive testimony in support of this resolution and recommends adoption.
BOARD OF TRUSTEES REPORT 11 - METHADONE
CLINICS AND PRESCRIPTION DRUG MONITORING

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that the Recommendation in Board of Trustees Report 11 be amended by insertion and deletion on page 6, line 10 to read as follows:

That our American Medical Association (AMA) seek changes to allow states the flexibility to require opioid treatment programs methadone clinics to report to prescription monitoring programs.

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that the recommendations contained in Board of Trustees Report 11 be adopted as amended and the remainder of the report be filed.

RECOMMENDATION C:

Mr. Speaker, your Reference Committee recommends that the title of Board of Trustees Report 11 be changed to read as follows:

OPIOID TREATMENT AND PRESCRIPTION DRUG MONITORING PROGRAMS

HOD ACTION: Board of Trustees Report 11 adopted as amended and the remainder of the report filed.

Report 11 of the Board of Trustees reviews the current status and guidelines for methadone treatment facilities, the regulations governing their operation, and the diversity of state-based prescription drug monitoring programs (PMP). Additionally, the safety issues surrounding the use of methadone in clinical practice, as well as the potential risks and value of including patient information from methadone treatment facilities in PMP-reporting systems are addressed. This report recommends that our AMA seek changes to allow states the flexibility to require methadone clinics to report to prescription monitoring programs.

Considerable support was offered for BOT Report 11. Some cautions were raised regarding the fact that each state prescription monitoring program (PMP) is somewhat different, and that patients who are enrolled in opioid treatment programs are subject to stigma. Ultimately, your Reference Committee believes that providing information on such patients to state-based PMPs is in the public interest. A change in federal regulations will be required to allow this objective. Replacement of the term "methadone
clinics” with “opioid treatment programs” is more inclusive and will also capture patients
who are being treated with buprenorphine.

(9) RESOLUTION 502 – THE USE OF ATYPICAL
ANTIPSYCHOTIC MEDICATION IN PEDIATRIC
PATIENTS

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that
the first Resolve of Resolution 502 be amended by
insertion and deletion on page 2, line 6 to read as follows:

RESOLVED, That our American Medical Association ask
the Council on Science and Public Health to prepare a
report on the increased safety and appropriate use of
atypical antipsychotic medications in children and
adolescents. (Directive to Take Action)

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that
the second Resolve of Resolution 502 be deleted.

RECOMMENDATION C:

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 AMA: (1) ask the Council on Science and Public Health to
prepare a report on the increased use of atypical antipsychotic medications in children
and adolescents; and (2) ask the Council on Science and Public Health to prepare a
series of recommendations for physicians and parents regarding the safe and
appropriate use of these medications in pediatric patients.

Your Reference Committee heard a range of testimony on this resolution. Several
individuals and groups testified to the need for an unbiased report on the serious
adverse effects of atypical antipsychotic medications, which are often used off-label and
may be the only effective therapy in some adolescent patients. Some concern was
voiced suggesting that this topic is specialized and that it is therefore more appropriate
for the American Academy of Child and Adolescent Psychiatry to undertake a report.
The Council on Science and Public Health testified that it would support the request for a
report. Since the conclusions of a report on this topic are unknown at this time, your
Reference Committee believes that the Council may be unable to “prepare a series of
recommendations on the safe and appropriate use” of antipsychotic medications in
children (as asked in Resolve 2), and therefore recommends that resolve 2 be deleted.
RESOLUTION 503 - INSUFFICIENT SLEEP IN ADOLESCENTS

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that the first Resolve of Resolution 503 be amended by deletion on line 12 to read as follows:

RESOLVED, That our American Medical Association identify adolescent insufficient sleep and sleepiness as a major public health issue (Directive to Take Action)

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that the second Resolve of Resolution 503 be deleted.

RECOMMENDATION C:

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

HOD ACTION: Resolution 503 adopted as amended.

Resolution 503 asks that our AMA: (1) identify adolescent insufficient sleep and sleepiness as a major public health issue; (2) support the further development and evaluation of systemic and educational approaches to address the problem of insufficient sleep and daytime sleepiness in adolescents; and (3) support education about sleep health as a standard component of care for adolescent patients.

Testimony supported the notion that a significant percentage of the adolescent population suffers from some degree of sleep deprivation, and that sleep deprivation is associated with a number of health problems, such as depression and obesity. Your Reference Committee believes that this problem should be acknowledged.

RESOLUTION 504 - SAFETY AND LABELING OF PHARMACEUTICALS AND NUTRACEUTICALS

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that Substitute Resolution 504 be adopted.

SAFETY AND LABELING OF DRUGS AND DIETARY SUPPLEMENTS
RESOLVED, That Policy H-100.980 Food and Drug Administration be reaffirmed. (Reaffirm HOD Policy)

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that Policy H-115.988 be amended by insertion to read as follows:

H-115.988 Qualitative Labeling of All Drugs

The AMA supports efforts to promote the qualitative labeling of all drugs and dietary supplements, requiring both active and inactive ingredients of over-the-counter and prescription drugs and dietary supplements to be listed on the manufacturer's label or package insert.

HOD ACTION: Substitute Resolution 504 adopted.

Resolution 504 asks that our AMA: (1) advocate that the Food and Drug Administration (FDA) be funded and staffed to adequately inspect and ensure safety of all pharmaceuticals and nutraceuticals, including over-the-counter products, consumed in the United States; and (2) advocate that the FDA require labeling of all pharmaceuticals and nutraceuticals with their ingredients and their respective countries of origin.

Testimony was mixed on the practicality and wisdom of adopting this resolution. Support for requiring country of origin labeling for ingredients of pharmaceuticals and "nutraceuticals" reflected concerns about the damage associated with adulterated heparin products, and the potential for counterfeit medications to make their way into the U.S. market; hazards also may be associated with dietary supplements. Testimony also noted that the term "nutraceuticals" is one that has been coined by the industry and is not an official term reflected in current regulations. Furthermore, different statutes govern the regulation of prescription drugs and dietary supplements, with the latter regulated as foods. Your Reference Committee is aware that prescription drugs sold in the U.S. are subject to good manufacturing practice regulations whether they are made in whole or part in the U.S. Manufacturers are required to approve or reject all ingredients, including those provided by another company. Your Reference Committee views the issues raised by Resolution 504 as one of assuring the safety of drug products and dietary supplements sold in the U.S. Country of labeling origin would not seem to offer any assurance, especially given that the majority of active ingredients are currently imported. Accordingly, your Reference Committee urges reaffirmation and amendment of two current AMA policies that adequately address the issues raised by Resolution 504.

The HOD Policy recommended for reaffirmation is:

H-100.980 Food and Drug Administration

(1) AMA policy states that a strong and adequately funded FDA is essential to ensuring that safe and effective medical products are made available to the American public as efficiently as possible. (2) Our AMA: (a) continue to monitor and respond appropriately to legislation that affects the FDA and to regulations proposed by the FDA; (b) continue to
work with the FDA on controversial issues concerning food, drugs, biologics, radioactive
tracers and pharmaceuticals, and devices to try to resolve concerns of physicians and to
support FDA initiatives of potential benefit to patients and physicians; and (c) continue to
affirm its support of an adequate budget for the FDA so as to favor the agency's ability to
function efficiently and effectively. (3) Our AMA will continue to monitor and evaluate
proposed changes in the FDA and will respond as appropriate. (Sub. Res. 548, A-92;
BOT Rep. 32, A-95; BOT Rep. 18, A-96; Reaffirmed: BOT Rep. 7, I-01; Reaffirmation I-
07)

(12) RESOLUTION 505 - THE DRY ANTIBIOTIC PIPELINE
AND THE 10 X ’20 COMMITMENT

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that
the second Resolve of Resolution 505 be amended by
insertion and deletion on page 2, line 14 to read as follows:

RESOLVED, That our AMA endorse the 10 x ’20 initiative
(10 new antibiotics by 2020) and support efforts to bring
together experts from the industrial, medical, scientific,
policy, regulatory, and financial communities to determine
and adopt the right combination of incentives needed to
create a sustainable antibiotic research and development
enterprise. (Directive to Take Action)

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that
Resolution 505 be adopted as amended.

RECOMMENDATION C:

Mr. Speaker, your Reference Committee recommends that
the title of Resolution 505 be changed to read as follows:

THE 10 x ‘20 INITIATIVE (10 NEW ANTIBIOTICS BY
2020)

HOD ACTION: Resolution 505 adopted as amended with a
change in title.

Resolution 505 asks that our AMA: (1) support efforts to educate physicians, the
Administration, Congress, and the public about the problem of antimicrobial resistance
and the lack of new antibiotics in the drug development pipeline; and (2) endorse the 10
x ’20 initiative and support efforts to bring together experts from the industrial, medical,
scientific, policy, regulatory, and financial communities to determine and adopt the right
combination of incentives needed to create a sustainable antibiotic R&D enterprise.
Your Reference Committee heard fully supportive testimony for this resolution. Several comments underscored the urgent need for new antibiotics, and acknowledged the past efforts of the AMA in supporting new antibiotic initiatives. Your Reference Committee agreed with a suggestion to clarify what the “10 x ’20 Initiative” means, and also believed that the title should be changed to clearly reflect the content of the resolution.

(13) RESOLUTION 508 - PRESCRIPTION LEAFLETS

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Substitute Resolution 508 be adopted.

RESOLVED, That our American Medical Association monitor the ongoing re-evaluation of how consumer medication information is designed and provided in the U.S. and provide input to ensure that such documents are clinically useful, written at the appropriate literacy level, and promote patient adherence.

HOD ACTION: Substitute Resolution 508 adopted.

Resolution 508 asks that our AMA work with the Food and Drug Administration, National Association of Boards of Pharmacy, prescribers, The Pharmaceutical Research and Manufacturers of America, developers of written and/or on-line consumer medication information, consumers and others deemed appropriate to set standards for consumer medication information that meets existing FDA criteria for usability and which is not diluted by consumer coupons or other irrelevant in-store advertising.

Testimony reflected concerns with the current variability in information contained in consumer medication information that is provided when prescription medications are dispensed, and secondarily the appropriateness of additional coupons or in-store advertising that may be supplied at the same time. Previously, the content and format of such leaflets were provided by the private sector. Recently, the FDA determined that the private sector has failed to meet its responsibility for providing useful prescription medication information to consumers. Accordingly, because the FDA is currently re-evaluating the entire issue of consumer medication information, and is anticipating moving toward a so-called “single document” solution, your Reference Committee has crafted a substitute resolution that is more appropriate at this time.

(14) RESOLUTION 509 - US TASK FORCE ON PREVENTIVE MEDICINE - BREAST SCREENING MAMMOGRAPHY

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that HOD Policy H-525.993 be amended in lieu of the first Resolve of Resolution 509, to read as follows:
H-525.993 Mammography Screening in Asymptomatic Women Forty Years and Older

1. Our AMA strongly endorses the positions of the American College of Obstetrics and Gynecology, the American Cancer Society, and the American College of Radiology that all women have screening mammography as per current guidelines supports guidelines regarding screening mammography, clinical breast examination, and self-breast examination that are evidence-based and that encourage physicians to determine the frequency and appropriateness of such screening procedures based on individual patient characteristics. 2. Our AMA opposes the use of guidelines by the federal government and insurance companies to restrict a patient’s access to physician-recommended screening procedures. 3. Our AMA favors participation in and support of the efforts of the professional, voluntary, and government organizations to educate physicians and the public regarding the value of screening mammography in reducing breast cancer mortality. 4. Our AMA advocates remaining alert to new epidemiological findings regarding age-specific breast cancer mortality reduction following mammography screening. 4. Based on recent summary data our AMA recommends annual screening mammograms and continuation of clinical breast examinations in asymptomatic women 40 years and older. 5. Our AMA encourages the periodic reconsideration of these recommendations as more epidemiological data become available. 6. Our AMA supports seeking common recommendations with other organizations. 7. Our AMA reiterates its longstanding position that all medical care decisions should occur only after thoughtful deliberation between patients and physicians.

RECOMMENDATION B:
Mr. Speaker, your Reference Committee recommends that HOD Policy H-410.967 Guide to Clinical Preventive Services be reaffirmed.

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

Mr. Speaker, your Reference Committee recommends that
the title of Resolution 509 be changed to read as follows:

BREAST CANCER SCREENING

HOD ACTION: Original Resolution 509: Resolve 1 referred
for decision; Resolve 2 adopted.

Resolution 509 asks that our AMA: (1) recommend that physicians and patients continue
to follow the guidelines of the American Cancer Society regarding screening
mammography and patient breast self-examination; and (2) encourage government
panels and task forces dealing with specific disease entities to have representation by
physicians with expertise in those diseases.

Your Reference Committee heard extensive and wide-ranging testimony on this
resolution. The majority of the testimony centered on the conflicting recommendations
on whether women ages 40-49 should receive routine screening mammography.
Several of those testifying supported the resolution, along with the American Cancer
Society guidelines that recommend screening mammography beginning at age 40.
Several others supported the recommendations by the US Preventive Services Task
Force that routine screening mammography begin at age 50 with screening in younger
women guided by individual patient-physician dialogue. A large number testified that our
AMA should not be in the position of choosing specific recommendations or guidelines to
support. Instead, our AMA should support guidelines that are evidence-based, and that
acknowledge a physician’s right to tailor screening and treatment based on individual
patient characteristics. The Council on Science and Public Health offered language
amending HOD Policy H-525.993 (Mammography Screening in Asymptomatic Women
Forty Years and Older) to reflect those thoughts. Testimony was overwhelmingly
supportive of Resolve 2, which encourages panels making recommendations and
guidelines to include representation by physicians with expertise in the disease area
being addressed.

Several of those who testified recommended that the resolution be referred so that the
AMA could study the issue of conflicting guidelines, what they mean for practicing
physicians, and possible use by the government and insurance companies in coverage
decisions. Your Reference Committee believes that HOD Policy 410.967 (Guide to
Clinical Preventive Services) addresses well the AMA’s position on how guidelines
should be used by physicians (i.e., that guidelines should not take the place of clinical
judgment and the need for individualizing care). Also, the language provided by the
Council on Science and Public Health, amending HOD Policy H-525.993
(Mammography Screening in Asymptomatic Women Forty Years and Older), addresses
the concern that guidelines could be used by the government and insurance companies
to restrict patient access to screening mammography.

The HOD Policy recommended for reaffirmation is:

H-410.967 Guide to Clinical Preventive Services
The AMA: (1) recommends the USPSTF Guide to Clinical Preventive Services to clinicians and medical educators as one resource for guiding the delivery of clinical preventive services. The Guide should not be construed as AMA policy on screening procedures and should not take the place of clinical judgment and the need for individualizing care with patients; physicians should weigh the utility of individual recommendations within the context of their scope of practice and the situation presented by each clinical encounter; (2) will continue to encourage the adoption of practice guidelines as they are developed based on the best scientific evidence and methodology available; and (3) will continue to promote discussion, collaboration, and consensus among expert groups and medical specialty societies involved in preparation of practice guidelines. (CSA Rep. 1, A-97; Modified and Reaffirmed: CSAPH Rep. 3, A-07)

(15) RESOLUTION 515 - PHARMACIES AS COLLECTION POINTS TO PROPERLY DISPOSE OF UNUSED PRESCRIPTION AND OVER-THE-COUNTER (OTC) DRUGS

RECOMMENDATION:

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

PROPER DISPOSAL OF UNUSED PRESCRIPTION AND OVER-THE-COUNTER (OTC) DRUGS

RESOLVED, That our AMA support initiatives designed to promote and facilitate the safe and appropriate disposal of unused medications. (New HOD Policy)

HOD ACTION: Substitute Resolution 515 adopted.

Resolution 515 asks that our AMA work with interested organizations and appropriate state agencies to promote education regarding the storage and disposal of unused medications.

Your Reference Committee heard unanimous supportive testimony for the intent of this resolution. There were some comments that the title of the resolution did not match the resolve, with the title referencing pharmacies as collection points, and the resolve addressing education regarding the storage and disposal of unused medications. The sponsors of the resolution confirmed that the intent is to create a collection point for unused medications. A substitute resolution supporting the safe and appropriate disposal of unused medications in general was suggested. Your Reference Committee believes that this substitute resolution broadly encompasses the intent of the resolution.
RESOLUTION 516 - DEEP VEIN THROMBOSIS

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that Resolution 516 be amended by deletion of the first Resolve.

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that the second Resolve of Resolution 516 be amended by insertion and deletion on lines 20-23 to read as follows:

RESOLVED, That our AMA draft a letter to urge the Federal Aviation Administration and to individual airlines to provide requesting that more comprehensive educational modalities detailing DVT prevention, including seat-back inserts, be included for all long-duration domestic and international airline flights. (Directive to Take Action)

RECOMMENDATION C:

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

RECOMMENDATION D:

Mr. Speaker, your Reference Committee recommends that the title of Resolution 516 be changed to read as follows:

DEEP VEIN THROMBOSIS AS A COMPLICATION OF AIR TRAVEL

HOD ACTION: Resolution 516 adopted as amended with a change in title.

Resolution 516 asks that our AMA: (1) intensify educational efforts regarding prevention of deep vein thrombosis (DVT) and pulmonary embolism; and (2) draft a letter to the Federal Aviation Administration and to individual airlines requesting that more comprehensive educational modalities detailing DVT prevention, including seat-back inserts, be included for all long-duration domestic and international airline flights.

Testimony was divided on the need and value of this resolution. The Council on Science and Public Health previously addressed this issue in 2004. Uncertainty was expressed about the risks associated with air travel per se, the time limit above which risks begin to measurably increase, and the need to buttress current educational approaches used by airlines regarding the risk for deep venous thrombosis during extended flights. Both seat back cards and video presentations have been employed. A meta analysis on the risk for DVT associated with air travel was recently published, and the WHO is currently...
conducting a more extensive study on adverse outcomes related to DVT in association with air flight.

(17) RESOLUTION 519 - GLOBAL TRACKING SYSTEM OF ZOONOTIC DISEASES

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Substitute Resolution 519 be adopted.

RESOLVED, That our American Medical Association work with the American Veterinary Medical Association and other relevant stakeholders to encourage the U.S. Departments of Health and Human Services, Agriculture, Interior, and other appropriate federal and state agencies to take the lead in establishing a robust, coordinated, and effective global surveillance system of zoonotic diseases in humans and syndromic outbreaks in animals, thereby enhancing collaboration of human and animal health sectors and resulting in improved early detection and response. (Directive to Take Action)

HOD ACTION: Substitute Resolution 519 adopted.

Resolution 519 asks that our AMA work with the federal government and the Centers for Disease Control and Prevention to take the lead, working with global health organizations, to establish a global surveillance system of zoonotic diseases in both humans and animals with better collaboration of human and animal health sectors resulting in improved early detection and responses.

The sponsors of this resolution introduced a substitute resolution that shifted the recommendation that the AMA lead a global surveillance system for zoonotic diseases, to more appropriate federal and state agencies, but preserved the request that the AMA work with such agencies. Testimony was overwhelmingly supportive of this substitute resolution, and noted the AMA’s current involvement in the One Health Initiative that addresses the intersection between human and animal health and the environment.

(18) RESOLUTION 522 - PARTICIPATION IN AN INTERNATIONAL PAIN SUMMIT

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that the first Resolve of Resolution 522 be amended by deletion on line 22 to read as follows:
RESOLVED, That our American Medical Association endorse and seek to participate in the International Association for the Study of Pain (IASP) International Pain Summit to be held in Montreal, Canada, on September 3, 2010 (Directive to Take Action); and be it further

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that the second Resolve of Resolution 522 be amended by deletion on line 26 to reads as follows:

RESOLVED, That our AMA facilitate and encourage the participation of affiliate pain specialty societies, the American Board of Medical Specialties, the Accreditation Council for Graduate Medical Education, the Association of American Medical Colleges, and other relevant organizations in the IASP Pain Summit.

RECOMMENDATION C:

Mr. Speaker, your Reference Committee recommends that Resolution 522 be adopted as amended.

HOD ACTION: Resolution 522 adopted as amended.

Resolution 522 asks that our AMA: (1) endorse and seek to participate in the International Association for the Study of Pain (IASP) International Pain Summit to be held in Montreal, Canada, on September 3, 2010; (2) facilitate and encourage the participation of affiliate pain specialty societies, the American Board of Medical Specialties, the Accreditation Council for Graduate Medical Education, the Association of American Medical Colleges, and other relevant organizations in the IASP Pain Summit.

Testimony noted that a special symposium (International Pain Summit) will be hosted by the International Association for the Study of Pain in Montreal in September 2010. A plea was made for the AMA to endorse and actively participate in this conference, and to encourage the participation of important medical specialty societies, affiliated medical education organizations, and other relevant organizations. This request follows on the heels of a national pain summit organized by the Pain and Palliative Medicine Specialty Section Council at I-09. Your Reference Committee agrees that participation in the Montreal summit would be valuable and has offered two amendments to clarify the expectations for the AMA as a whole.
RESOLUTION 523 - THE DECADE OF PAIN CONTROL AND RESEARCH

RECOMMENDATION:

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

THE DECADE OF PAIN CONTROL AND RESEARCH

RESOLVED, That our American Medical Association recognize those responsible for the Decade of Pain Control and Research, and acknowledge their many achievements. (Directive to Take Action)

HOD ACTION: Substitute Resolution 523 adopted.

Resolution 523 asks that our AMA: (1) recognize and commend those responsible for the Decade of Pain Control and Research; and (2) acknowledge the many achievements of the Decade of Pain Control and Research including: growth in the overall number of Pain Medicine specialists and the establishment of an interstate network of Pain Medicine physicians; increasing acceptance of Pain Medicine as a medical specialty; improved appreciation and understanding of the neurophysiological and neuropathological processes of pain; congressional bills mandating pain care, education, and research in the military and the Department of Veterans Affairs (VA); efforts to establish a Division of Pain Medicine within the National Institutes of Health (NIH); convening of a National Pain Summit endorsed by our AMA and comprised of over 30 AMA specialty societies with an interest in pain care; the development of Pain Medicine and the Journal of Pain into top-tier journals; formal international liaisons in Pain Medicine, including the Pain Medicine journal’s agreements with the International Spine Intervention Society (ISIS), the Faculty of Pain Medicine of the Australian and New Zealand College of Anesthetists (FPM/ANZCA), and the Chinese edition of Pain Medicine; the recognition of the specialty of Pain Medicine in China and Australia; the convening of a National Pain Summit meeting in Australia; endeavors of the Pain Care Coalition to advocate for improved access to pain care and research; establishment of Pain Safe, a program to reduce inadvertent deaths and improve pharmacological treatment of persistent pain, by the National Pain Foundation and American Pain Foundation; establishment of the Pain Care Forum by the American Pain Foundation; formal proposals by the American Board of Pain Medicine for ABMS recognition of Pain Medicine as a distinct specialty; increase in international awareness, research, advocacy, and education of Pain Medicine; and the growth of specialty societies to support this.

Testimony was limited to the sponsor of this resolution. Your Reference Committee concurs that several successes have accompanied promulgation of the Decade of Pain Control and Research, and supports general acknowledgement of the key roles played by leaders of this initiative.
(20) RESOLUTION 526 (LATE 1001) - GENE PATENTS AND ACCESSIBILITY OF GENE TESTING

RECOMMENDATION A:

Mr. Speaker, your Reference Committee recommends that the first Resolve of Resolution 526 be amended by deletion on page 2, lines 16-17 to read as follows:

RESOLVED, That our American Medical Association oppose the future issuance and enforcement of patents on human genes and their naturally-occurring mutations (New HOD Policy; and be it further

RECOMMENDATION B:

Mr. Speaker, your Reference Committee recommends that Resolution 526 be adopted as amended.

HOD ACTION: Resolution 526 adopted as amended.

Resolution 526 asks that our AMA: (1) oppose the future issuance and enforcement of patents on human genes and their naturally-occurring mutations; (2) support legislation requiring that existing gene patents be broadly licensed so as not to limit access through exclusivity terms, excessive royalties or other unreasonable terms, and (3) support legislation that would exempt from claims of infringement those who use patented genes for medical diagnosis and research.

Your Reference Committee heard mostly supportive testimony for this resolution. The sponsors of the resolution and several others testified to the need for gene patents to be prohibited so that physicians and researchers can freely use genetic information to discover new, effective, and affordable tests and treatments. The Council on Science and Public Health noted that the resolution is consistent with recent AMA activities and public comments regarding gene patenting. The Council also suggested removing the reference to future patents from Resolve 1 so that our AMA opposes all gene patents, and not just those issued in the future. Limited testimony was offered regarding the possibility that prohibition of gene patents could stifle innovation; however, your Reference Committee believes that physician and researcher access to genetic information is of the utmost importance to support quality patient care.

(21) RESOLUTION 521 - STRICTER OVERSIGHT OF HOMEOPATHIC PRODUCTS BY THE FOOD AND DRUG ADMINISTRATION

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Resolution 521 be referred for decision.
HOD ACTION: Resolution 521 referred for decision.

Resolution 521 asks that our AMA seek improved oversight of homeopathic/naturopathic products by the Food and Drug Administration or other appropriate agencies, especially with regards to purity and safety.

The only testimony offered on this resolution referred to the problems encountered with adverse reactions to a specific homeopathic product used for colds. The resolution asks for improved FDA oversight of homeopathic and naturopathic products. Based on the way this resolution is written, it is not entirely clear what products would be included under these categories, or the specific regulatory authorities and enforcement mechanisms. For example, the Homeopathic Pharmacopeia of the U.S. is the official compendium of homeopathic drug products recognized by the FDA. Homeopathy also receives special status under the Food Drug and Cosmetic Act.

(22) RESOLUTION 507 - FORENSIC TOXICOLOGY
DETERMINATIONS MADE BY MEDICAL EXAMINERS/CORONERS

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Resolution 507 not be adopted.

HOD ACTION: Resolution 507 not adopted.

Resolution 507 asks that our AMA: (1) support forensic investigations and determinations of post-mortem samples by state medical examiners and coroners of all unknown and/or drug-related deaths be achieved through a standardized approach; (2) seek regulatory or legislative changes to ensure a proper and medically appropriate multi-disciplinary approach to the evaluation/determination of all suspected drug-related deaths; and (3) take appropriate actions to ensure oversight and standardization for forensic toxicological investigations by State Medical Examiners and Coroners.

This resolution encountered strong testimony against adoption. Individuals within the field of forensic toxicology and pathology testified that they take a multidisciplinary approach when conducting an examination and consult with relevant and appropriate specialties when necessary. They consider the circumstances surrounding the death, the history of the patient, and the autopsy results (including toxicology and other studies). Medical examiners currently utilize toxicology surveillance programs including the National Association of Pediatric Toxicology Registry, the FDA Med Watch Program, the Drug Abuse Warning Network, the DEA’s High Intensity Drug Trafficking Program, and the CDC’s National Violent Death Reporting System. Also, certification programs are in place by organizations such as the American Board of Pathology, the American Board of Forensic Toxicology and the National Association of Medical Examiners.
(23) RESOLUTION 514 - ORTHOPEDIC IMPLANT EXTRACTION

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Resolution 514 not be adopted.

HOD ACTION: Resolution 514 not adopted.

Resolution 514 asks that our AMA petition the Food and Drug Administration, or other appropriate agency, to require all implant manufacturers to develop implant insertion and extraction devices which can be used interchangeably in any surgical implant procedure.

Your Reference Committee heard strong testimony against this resolution. Testimony noted that although the intent of the resolution is admirable, the many different types of devices would make interchangeability nearly impossible (e.g., a universally applicable extraction device could not be used with any implant). Several individuals cited the concern that interchangeable devices would stifle innovation, and that the variation of devices within the field has led to improvements. Testimony in support of this resolution cited the desire to lower health care costs by standardization of devices, wherever possible. However, the FDA provided testimony that they do not have the regulatory authority to require that all manufacturers develop interchangeable insertion and extraction devices.

(24) RESOLUTION 520 - ENSURE SAFETY OF BOTTLED WATER

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Resolution 520 not be adopted.

HOD ACTION: Resolution 520 not adopted.

Resolution 520 asks that our AMA: (1) work with the US Food and Drug Administration to ensure stringent standards for bottled water comparable to the requirements for tap water stipulated by the US Environmental Protection Agency; and (2) work with the US Food and Drug Administration to ensure that the consumers of bottled water are able to know the origin, treatment, and any potential chemical pollutants routinely tested for in tap water.

Most testimony opposed this resolution. One prominent concern was that the FDA does not regulate bottled water to the same degree that the Environmental Protection Agency (EPA) regulates tap water. The FDA testified that bottled water is subject to specific regulations established under current Good Manufacturing Practice Regulations (cGMP). These regulations require that bottled water be safe and that it be processed, bottled, held and transported under sanitary conditions. Processing practices under the cGMP regulations include protection of the water source from contamination, sanitation at the
bottling facility, quality control, and sampling, and testing of the source water and the
final product for microbiological, chemical and radiological contaminants.

(25) RESOLUTION 501 - DIETARY SUPPLEMENTS

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that
Policy H-150.954 be reaffirmed in lieu of Resolution 501.

HOD ACTION: Policy H-150.954 be reaffirmed in lieu of
Resolution 501.

Resolution 501 asks our AMA to encourage passage of legislation that would lead to
government supervision to ensure content and purity of over-the-counter supplements,
while continuing to otherwise support the Dietary Supplement Health and Education Act
passed by Congress that does not evaluate product safety or efficacy.

Testimony reflected continuing concerns about the safety and purity of dietary
supplements marketed under the Dietary Supplement Health and Education Act
(DSHEA). The asks in Resolution 501 are in fact less stringent and expansive than
current policy on this topic, which urges Congress to revisit DSHEA and strengthen
controls on product safety. The potential value of the United States Pharmacopeia's
voluntary Dietary Supplement Verification Program also was noted.

The HOD Policy recommended for reaffirmation is:

H-150.954 Dietary Supplements and Herbal Remedies
(1) Our AMA will work with the FDA to educate physicians and the public about FDA's
MedWatch program and to strongly encourage physicians and the public to report
potential adverse events associated with dietary supplements and herbal remedies to
help support FDA's efforts to create a database of adverse event information on these
forms of alternative/complementary therapies. (2) Our AMA continues to urge Congress
to modify the Dietary Supplement Health and Education Act to require that (a) dietary
supplements and herbal remedies including the products already in the marketplace
undergo FDA approval for evidence of safety and efficacy; (b) meet standards
established by the United States Pharmacopeia for identity, strength, quality, purity,
packaging, and labeling; (c) meet FDA postmarketing requirements to report adverse
events, including drug interactions; and (d) pursue the development and enactment of
legislation that declares metabolites and precursors of anabolic steroids to be drug
substances that may not be used in a dietary supplement. (3) Our AMA work with the
Federal Trade Commission (FTC) to support enforcement efforts based on the FTC Act
and current FTC policy on expert endorsements. (4) That the product labeling of dietary
supplements and herbal remedies contain the following disclaimer as a minimum
requirement: "This product has not been evaluated by the Food and Drug Administration
and is not intended to diagnose, mitigate, treat, cure, or prevent disease." This product
may have significant adverse side effects and/or interactions with medications and other
dietary supplements; therefore it is important that you inform your doctor that you are
using this product. (5) That in order to protect the public, manufacturers be required to
investigate and obtain data under conditions of normal use on adverse effects,
contraindications, and possible drug interactions, and that such information be included on the label. (6) Our AMA continue its efforts to educate patients and physicians about the possible ramifications associated with the use of dietary supplements and herbal remedies. (Res. 513, I-98; Reaffirmed: Res. 515, A-99; Amended: Res. 501 & Reaffirmation I-99; Reaffirmation A-00; Reaffirmed: Sub. Res. 516, I-00; Modified: Sub. Res. 516, I-00; Reaffirmed: Sub. Res. 518, A-04; Reaffirmed: Sub. Res. 504, A-05; Reaffirmation A-05; Reaffirmed in lieu of Res. 520, A-05)

(26) RESOLUTION 524 - PHARMACEUTICAL AND BIOLOGICAL UTILIZATION BEYOND EXPIRATION DATE

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that Policy H-115.983 be reaffirmed in lieu of Resolution 524.

HOD ACTION: Resolution 524 not adopted.

Resolution 524 asks that our AMA: (1) establish a dialogue with the Food and Drug Administration aimed at encouraging that the pharmaceutical/biological industry adopt guidelines for establishing expiration dates consistent with their products’ efficacy; and (2) that specifics of any drug product stability (in percentage) post expiration dates in 3-month increments for two years be included in the package insert.

Limited and truncated testimony was offered in explanation of the need for this resolution. Your Reference Committee is aware that pharmaceutical manufacturers are required to place an expiration date on the container/label of a drug product as a prerequisite to marketing the product in the United States. Expiration dates are determined by stability assessments that follow scientifically based procedures that have been harmonized by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) guidance. Expiration dates only apply when the drug product is stored under defined conditions. For most U.S. drug products, expiration dating ranges from 12 to 60 months from the time of original manufacture. The Guidelines referred to in Resolve 1 already exist. Existing policy (H-115.983) asks that expiration dates be based on scientifically based stability testing and that it should be determined if lengthening such dates can provide clinical and/or economic benefit, and if so, companies should conduct longer stability testing. The asks in Resolve 2 would not seem to be economically feasible under the current regulatory framework for new prescription drugs.

The HOD Policy recommended for reaffirmation is:

H-115.983 Expiration Dates and Beyond-Use Dates of Prescription Drug Products

Our AMA: (1) supports the inclusion of expiration dates on the containers/labels of prescription drug products and recommends that expiration dates be determined by pharmaceutical manufacturers using scientifically based stability testing with subsequent approval by the Food and Drug Administration (FDA); (2) urges the pharmaceutical industry, in collaboration with purchasers, the FDA, and the United States Pharmacopeia (USP), to determine whether lengthening of expiration dates will provide clinical and/or
economic benefits or risks for patients and, if this is the case, to conduct longer stability
testing on their drug products; (3) recommends that pharmacists place a beyond-use
date on the labeling of all prescription medications dispensed to patients, and that the
beyond-use date be based on the recommendations in the most recent edition of the
United States Pharmacopeia and National Formulary (currently USP 24-NF 19) (official
January 1, 2000); and (4) encourages the USP, in collaboration with pharmaceutical
manufacturers, pharmacy organizations, and the FDA, to continue to explore the
development of appropriate stability tests for the determination of scientifically sound
Appended: Res. 527 and Reaffirmed: Res. 520, A-00; Modified: CSA Rep. 1, A-01;
Reaffirmed: Res. 515, A-02; Reaffirmation A-07)

(27) RESOLUTION 525 - CONSISTENCY IN
PHARMACEUTICAL THERAPY

RECOMMENDATION:

Mr. Speaker, your Reference Committee recommends that
Policy H-125.984 Generic Drugs be reaffirmed in lieu of
Resolution 525.

HOD ACTION: Policy H-125.984 Generic Drugs be
reaffirmed in lieu of Resolution 525.

Resolution 525 asks that the AMA vigorously oppose any industry or government
initiative of existing requirement, proclamation and/or legislation that contradicts the
assessment of qualified medical practitioners, and thereby constrains the use of
consistently manufactured pharmaceutical products where medical evidence
categorically supports that use

The sole testimony on this item was a case report of a patient who suffered a
breakthrough seizure in temporal association with an episode of generic substitution.
The Council on Science and Public Health has generated two previous report on the
issue of generic substitution. Your Reference Committee is aware that the inference that
A-rated generic products can vary in bioequivalence from the innovator product by as
much as 40% is a common misconception and that based on the actual statistical method
used to evaluate bioequivalence, tested products that begin to deviate by more than a
mean value of 3 to 5% fail the bioequivalence test. Furthermore, physicians have the
ability to dictate which drug (brand or generic) is prescribed in all 50 states. Current
AMA Policy is rational and establishes the appropriate benchmark for clinical decision-

The HOD Policy recommended for reaffirmation is:

H-125.984 Generic Drugs

Our AMA believes that: (1) Physicians should be free to use either the generic or brand
name in prescribing drugs for their patients, and physicians should supplement medical
judgments with cost considerations in making this choice. (2) It should be recognized
that generic drugs frequently can be less costly alternatives to brand-name products. (3)
Substitution with Food and Drug Administration (FDA) "B"-rated generic drug products
(i.e., products with potential or known bioequivalence problems) should be prohibited by law, except when there is prior authorization from the prescribing physician. (4) Physicians should report serious adverse events that may be related to generic substitution, including the name, dosage form, and the manufacturer, to the FDA’s MedWatch program. (5) The FDA, in conjunction with our AMA and the United States Pharmacopoeia, should explore ways to more effectively inform physicians about the bioequivalence of generic drugs, including decisional criteria used to determine the bioequivalence of individual products. (6) The FDA should fund or conduct additional research in order to identify the optimum methodology to determine bioequivalence, including the concept of individual bioequivalence, between pharmaceutically equivalent drug products (i.e., products that contain the same active ingredient(s), are of the same dosage form, route of administration, and are identical in strength). (7) The Congress should provide adequate resources to the FDA to continue to support an effective generic drug approval process. (CSA Rep. 6, A-02; Reaffirmed: CSAPH Rep. 2, A-07; Reaffirmation A-08)
Mr. Speaker, this concludes the report of Reference Committee E. I would like to thank Susan L. Hubbell, MD, William Pease, MD, Ryan Ribeira, Steven Tharp, MD, David T. Walsworth, MD, and all those who testified before the Committee.

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