

## 2002 Annual Meeting of the American Medical Association

### Reports of the Council on Scientific Affairs

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**EDITOR'S NOTE:** *The Recommendations in these report summaries reflect AMA policy at the time the reports were adopted by the AMA House of Delegates. Consult the AMA PolicyFinder for the most recent AMA policy and directives.*

## 2002 AMA Annual Meeting

### Summaries and Recommendations of Council on Scientific Affairs Reports

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#### Bullying Behaviors Among Children and Adolescents (CSA Rep. 1, A-02)

##### Summary

**Objective.** To review the scope and nature of bullying among US children and adolescents, identify successful interventions to prevent or reduce bullying occurrences, and discuss the important role of physicians in addressing this behavior.

**Data Sources.** MEDLINE, PsychInfo, Educational Resource Information Center, and National Criminal Justice Reference Service databases were searched for English-language articles published from 1985 to 2002. Additional information was derived from manual review of references cited in relevant journal articles, reports, and textbooks. Information also was received from direct communication with federal agencies, medical specialty societies, mental health and other professional organizations, and recognized researchers in this field.

**Data Synthesis.** Bullying is defined as a negative behavior that involves (1) a pattern of repeated aggression; (2) deliberate intent to harm or disturb a victim despite apparent victim distress; and (3) a real or perceived imbalance of power (eg, due to age, strength, size), with the more powerful child or group attacking a physically or psychologically vulnerable victim. Bullies represent about 7% to 15% of sampled school-age populations; victims represent about 10%. Two percent to 10% of students are both bullies and victims. The prevalence of students involved in bullying is consistently higher for boys than girls in elementary schools, but for each gender the prevalence decreases during the junior high school years and continues to decrease into high school. Without intervention, bullying can lead to serious academic, social, emotional, and legal problems. Indicators of psychosocial and psychosomatic health vary according to bullying status. Studies of successful anti-bullying programs are scarce in the United States but evaluation data from other countries suggest that adopting a comprehensive approach in schools can change student behaviors and attitudes and increase adults' willingness to intervene.

**Conclusions.** Bullying encompasses a wide and complex span of abusive behaviors with potentially serious social and mental health consequences for victims and perpetrators. Children who are both bullies and victims may be at increased risk. Efforts to prevent or reduce bullying require involved and motivated parents, school administrators, teachers, and other adults with a positive interest in addressing this problem; firm and clear limits for unacceptable behavior; elimination of risk factors that promote this behavior; teaching children social and cognitive skills, problem-solving techniques, and anger management; supervision and monitoring of students' behavior; and clearly defined consequences for those who break the rules. Effective prevention also should focus on helping families improve parenting skills. Physicians have important roles in identifying at-risk patients, screening for psychiatric comorbidities, counseling families about the problem, and advocating for bullying and violence prevention in their communities.

## RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 2002 AMA Annual Meeting:

1. The AMA recognizes bullying as a complex and abusive behavior with potentially serious social and mental health consequences for children and adolescents. Bullying is defined as a pattern of repeated aggression; with deliberate intent to harm or disturb a victim despite apparent victim distress; and a real or perceived imbalance of power (eg, due to age, strength, size), with the more powerful child or group attacking a physically or psychologically vulnerable victim.
2. The AMA will advocate for federal support of research (a) for the development and effectiveness testing of programs to prevent or reduce bullying behaviors, which should include rigorous program evaluation to determine long-term outcomes; (b) for the development of effective clinical tools and protocols for the identification, treatment, and referral of children and adolescents at risk for and traumatized by bullying; (c) to further elucidate biological, familial, and environmental underpinnings of aggressive and violent behaviors and the effects of such behaviors; and (d) to study the development of social and emotional competency and resiliency, and other factors that mitigate against violence and aggression in children and adolescents.
3. The AMA urges physicians to (a) be vigilant for signs and symptoms of bullying and other psychosocial trauma and distress in children and adolescents; (b) enhance their awareness of the social and mental health consequences of bullying and other aggressive behaviors; (c) screen for psychiatric comorbidities in at-risk patients; (d) counsel affected patients and their families on effective intervention programs and coping strategies; and (e) advocate for family, school, and community programs and services for victims and perpetrators of bullying and other forms of violence and aggression.
4. The AMA will advocate for federal, state, and local resources to increase the capacity of schools to provide safe and effective educational programs by which students can learn to reduce and prevent violence. This includes: (a) programs to teach, as early as possible, respect and tolerance, sensitivity to diversity, and interpersonal problem-solving; (b) violence reduction curricula as part of education and training for teachers, administrators, school staff, and students; (c) age and developmentally appropriate educational materials about the effects of violence and aggression; (d) proactive steps and policies to eliminate bullying and other aggressive behaviors; and (e) parental involvement.
5. The AMA will advocate for expanded funding of comprehensive school-based programs to provide assessment, consultation, and intervention services for bullies and victimized students, as well as provide assistance to school staff, parents, and others with the development of programs and strategies to reduce bullying and other aggressive behaviors.
6. The AMA urges parents and other caretakers of children and adolescents to (a) be actively involved in their child's school and community activities; (b) teach children how to interact socially, resolve conflicts, deal with frustration, and cope with anger and stress; and (c) build supportive home environments that demonstrate respect, tolerance, and caring and that do not tolerate bullying, harassment, intimidation, social isolation, and exclusion.

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The following statement, recommended by the Council on Scientific Affairs, was adopted as an AMA directive at the 2002 AMA Annual Meeting:

The AMA will work with appropriate federal agencies, medical societies, the Alliance, mental health organizations, education organizations, schools, youth organizations, and others in a national campaign to change societal attitudes toward and tolerance of bullying, and advocate for multifaceted age and developmentally appropriate interventions to address bullying in all its forms.

NOTE: A revised version of this report has been published: Lyznicki JM, McCaffree MA, Robinowitz CB, for the Council on Scientific Affairs: Childhood bullying: implications for physicians. *Am Fam Physician*. 2004;70:1723-1728,1729-1730.

## **Childhood Asthma: Emerging Patterns and Prospects for Novel Therapies (CSA Rep. 2, A-02)**

### **Summary**

**Objectives.** This report examines some of the basic epidemiologic patterns underlying much of the recent interest in childhood asthma. Specifically, it examines trends in childhood asthma morbidity and mortality in the United States, reviews some of the factors associated with these emerging patterns, and explores therapeutic interventions to reduce childhood asthma.

**Methods.** A systematic review was conducted using the MEDLINE database for the years 1980 to 2001. English-language articles were selected based on their ability to provide information on (1) the definition and diagnosis of childhood asthma; (2) trends in the morbidity and mortality of childhood asthma; and (3) the epidemiology of childhood asthma. Further relevant articles and books were selected from the reference listings of the primary journal articles. Other sources included the National Center for Health Statistics, the President's Task Force on Environmental Health Risks and Safety Risks to Children, and the Epidemiology and Statistics Unit of the American Lung Association.

**Results.** When analyzed separately, trends in childhood asthma prevalence, hospitalizations, and mortality all point to a significant increase over the last 30 years. High levels of hospitalizations and/or mortality as a percentage of prevalence among children also suggest a high level of disease severity among children of all ages. Racial and ethnic minorities, boys, and children in urban areas suffer disproportionately from childhood asthma compared to other children. The trends noted are real and not simply an artifact of the way asthma is diagnosed, recorded, or analyzed. Increases in childhood asthma are also most likely the result of increases in risk factors associated with asthma morbidity and mortality. Caution is noted, however, because a definitive assessment of childhood asthma is limited by a number of factors, including problems with the data, a lack of consensus on definition, and an incomplete understanding of the epidemiology of the disease.

**Conclusions.** The United States is facing an epidemic of childhood asthma, especially in urban areas and among minority children. Furthermore, all indicators suggest that the prevalence of childhood asthma will continue to rise. Even if prevalence rates were to stabilize, childhood asthma would continue to be a profound public health concern. Despite the limitations in our understanding of the disease, more needs to be done to improve physician awareness and adherence to evidence-based asthma care guidelines. Physicians also need to support the development of performance measures and tools to promote appropriate assessment, classification, and treatment in accordance with the evidence-based recommendations. Finally, physicians may consider a number of promising strategies, including population-based approaches, to effectively treat the condition.

### **RECOMMENDATIONS**

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 2002 AMA Annual Meeting:

1. The AMA encourages physicians to make use of guidelines for the treatment of childhood asthma, including those contained in *Expert Panel Report II: Guidelines for the Diagnosis and Management of Asthma*, released by the National Heart, Lung, and Blood Institute, and the *Promoting Best Practice Guide for Management of Asthma in Children*, released by the American Academy of Allergy, Asthma and Immunology.
2. The AMA encourages physicians to (a) educate parents of children with asthma on the assessment and reduction of known risk factors for childhood asthma; and (b) where

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necessary refer patients and their families to comprehensive asthma education programs based on evaluated models.

3. The AMA encourages and supports public health departments to examine risk factors for childhood asthma and work with medicine to develop appropriate treatment and educational resources for physicians and for families with asthmatic children.

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA directives at the 2002 AMA Annual Meeting:

1. The AMA will continue to support the efforts of the Physician Consortium for Performance Improvement (The Consortium) to develop evidence-based performance measures for asthma care. Furthermore, that the AMA encourage The Consortium to explore the feasibility of performance measures for asthma care of children less than 5 years of age.
2. The AMA encourages the Centers for Disease Control and Prevention; the American Lung Association; the National Heart, Lung, and Blood Institute; the American Academy of Pediatrics; the American Academy of Family Physicians; and others to work together to develop a comprehensive and uniform definition of childhood asthma.
3. The AMA will educate physicians using existing communication channels on the problem of childhood asthma in the United States, including basic epidemiologic patterns underlying much of the recent interest in the environmental and demographic disparities in the prevalence of childhood asthma.
4. The AMA encourages the National Center for Health Statistics, the American Lung Association, and others to develop better data on the incidence and prevalence of childhood asthma morbidity and mortality, including complete demographic, environmental, and socioeconomic information.

**Safe Disposal of Used Needles and Syringes in the Community: Update on AMA Activities (CSA Rep. 3, A-02)**

**Summary**

**Objective.** To describe the activities of the American Medical Association on the issue of safe disposal of used needles and syringes in the community that have occurred since the adoption of Council on Scientific Affairs (CSA) Report 2 (A-01).

**Data Sources.** Information for this report was derived primarily from monthly conference calls held between primary stakeholders identified in CSA Report 2 (A-01), and from an organizational meeting held on February 22, 2002, in Washington, DC.

**Results.** The improper disposal of used sharps is an important public health problem. Populations exposed to the hazards posed by improperly disposed sharps in the community include children, sanitation workers, waste management employees, hospitality services employees, and others. These hazards include needlestick injuries, the cost and psychological impact of post-exposure counseling and prevention therapy, and the risk of transmission of bloodborne pathogens. Recognizing this problem, and following adoption of the recommendations of CSA Report 2 (A-01), the AMA is participating in two major activities to promote the safe community disposal of used needles and syringes: First, development of a problem-identification statement that will eventually be disseminated to local- and state-level stakeholders, news media, and the public, and, second, participation in an advisory group with the goal of establishing a coalition dedicated to the safe disposal of syringes and needles used by individuals in their homes and communities. As part of the AMA's efforts to promote awareness of this important public health problem, the CSA also presented an abstract based on CSA Report 2 (A-01) at the 2001 National HIV Prevention Conference, held in Atlanta, Georgia, in August 2001.

**Conclusions.** A final draft of the problem-identification statement has been completed, and it is anticipated that the Centers for Disease Control and Prevention will publish and print this statement. Supporting resources are being completed and will be available to provide to any party that responds to the call to action initiated by the problem-identification statement. Documentation establishing the Coalition for Safe Community Needle Disposal as a not-for-profit 501 c(3) corporation has been filed. Currently, business and policy boards are being formed. When the coalition is in place, a press release will be issued announcing its establishment and mission. All materials that are being prepared in support of the problem-identification statement should be completed at this point. Once these factors are in place, the problem-identification statement will be released, possibly in conjunction with a major press conference, to enhance the public and policy-makers' awareness of this important public health problem.

**RECOMMENDATIONS**

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA directives at the 2002 AMA Annual Meeting:

1. The AMA will continue to implement the recommendations of Council on Scientific Affairs Report 2 (A-01).
2. The AMA supports the mission of the newly established Coalition for Safe Community Needle Disposal. The mission statement is: "The Coalition for Safe Community Needle Disposal is dedicated to the safe disposal of syringes and needles used by individuals in their homes and communities. Every year, more than 2 billion needles and syringes are used outside of healthcare settings. Improperly disposed needles and syringes are a hazard to workers and the public. The coalition is a collaboration of businesses, community groups, and government

that promotes public awareness and solutions for safe disposal of needles and syringes in the community.”

3. The AMA supports the activities of the newly established Coalition for Safe Community Needle Disposal, which include producing the following materials: (a) guidelines for successful coalition building; (b) a list of frequently asked questions with appropriate answers for health care professionals regarding community needle and syringe disposal; (c) a discussion paper on the potential impact of the Occupational Safety and Health Administration’s Bloodborne Pathogens Standard on community safe needle and syringe disposal programs; (d) a list of programs already in existence, with the appropriate contact information; (e) a list of Web sites and listservs that detail and discuss community safe needle and syringe disposal programs; (f) fifty state-level guides describing and discussing all state legislation and regulations that may affect the implementation of a community safe needle and syringe disposal program; (g) a list of state and regional chapters/associations of the seven organizations working on the problem-identification statement; and (h) a list of peer-reviewed references on safe community needle and syringe disposal.

## **Pain Management Standards and Performance Measures (CSA Rep. 4, A-02)**

### **Summary**

**Objectives.** To summarize the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) pain management standards and physician reactions to them, and to describe efforts that have been initiated to clarify the standards, develop appropriate, evidence-based physician performance measures, and improve physician education in pain management techniques.

**Methods.** Literature searches were conducted in the PubMed/MEDLINE database for articles published between 2000 and 2002 using the search terms *joint commission*, *pain*, and *standards*. A search of *JAMA* and the American Medical Association Archives journals was conducted using the terms *joint commission* and *pain management*. Articles were selected that provided physician and organizational perspectives on the JCAHO pain management standards. The JCAHO World Wide Web site and the National Guideline Clearinghouse were also searched for relevant information. Personal correspondence and other communications between the AMA and JCAHO staff, AMA members, and constituent medical societies were consulted.

**Results.** Reaction in the professional literature to the July 2000 release of the JCAHO pain management standards has ranged from enthusiastic support, to concerns about challenges in implementation and the possible inappropriate intrusion of JCAHO into the patient-physician relationship. Much of the concern related to the new standards results from a misunderstanding of the actual requirements of the standards, due in part to the "examples of implementation" provided by the JCAHO. JCAHO surveyors are instructed to educate organizations about the intent of the pain management standards and to advise them of the level of expectation set forth by these standards. Initiatives are underway to clarify the standards, improve physician education in pain management, and develop evidence-based performance measures for pain management. These measures will be specific to cancer, back pain, and arthritis and will be based on clinical practice guidelines developed by relevant medical specialty societies and other organizations.

**Conclusions.** The AMA should continue to relay physician concerns and perceptions about the JCAHO pain management standards to the JCAHO. The JCAHO has taken steps to clarify the standards; the AMA must encourage and offer to assist in continued efforts. The Council on Scientific Affairs does not believe it is necessary for the AMA to appoint or convene a special committee or task force to evaluate the efficacy of the new JCAHO pain management standards. However, JCAHO does need to continue to clarify the actual requirements of the pain management standards and have its surveyors consult, educate, and advise organizations, as necessary, about acceptable means of implementing the pain management standards.

Continued improvement is needed in undergraduate medical education on pain management. The AMA Council on Medical Education should collaborate with relevant medical specialty organizations to improve undergraduate, graduate, and continuing education in pain management. The AMA should continue its support for the collaborative AMA-JCAHO-National Committee on Quality Assurance (NCQA) project to develop evidence-based performance measures for pain management.

### **RECOMMENDATIONS**

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA directives at the 2002 AMA Annual Meeting:

1. The AMA will continue to work with the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) and encourage continued collaborative efforts between the JCAHO and relevant medical specialty organizations to clarify the JCAHO pain management

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standards and to identify and clarify sources of information that are contributing to misinterpretation of the standards.

2. The AMA, through the Council on Medical Education, will continue to work with relevant medical specialty organizations to improve education in pain management in medical schools, residency programs, and continuing medical education programs.
3. The AMA, with or without partnership with other Joint Commission on Accreditation of Healthcare Organizations (JCAHO) corporate members, will appoint a committee or task force of regularly practicing health care professionals, including a multi-specialty panel of physicians, nurses and other mid-level practitioners, and administrators to objectively study and evaluate the efficacy to date of the new JCAHO Standard as it is currently being applied and identify who is responsible for its origins; and that this task force be urged to report back to the AMA Board of Trustees at an early date so that the Board can formulate recommendations to the Joint Commission.
4. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) should be encouraged to disseminate substantial additional clarification for the "examples of implementation" and eliminate them from the accreditation manuals and other publications.

## Improving the Quality of Geriatric Pharmacology (CSA Rep. 5, A-05)

### Summary

**Objectives.** To review the dimensions of medication use in the elderly, including the effects of aging on drug disposition, participation of the elderly in clinical trials, drug prescribing and utilization, assessment of prescribing appropriateness, adverse effects, and compliance.

**Methods.** Literature searches were conducted in the MEDLINE database for English-language articles published between 1985 and February 2002 using the search terms *aged* or *aging* or *geriatrics* in combination with *drug therapy; prescriptions, drug; pharmacokinetics; drug utilization review; pharmacology, clinical; self medication; or pharmaceutical services*. A total of 1686 citations were identified and 503 were retrieved for analysis. Additional references were culled from the bibliographies of these references.

**Results.** Patients  $\geq$  65 years of age take more drugs than younger patients. When over-the-counter drugs and dietary supplements are included, 43% of men and 57% of women take 5 or more medications weekly. This high rate of drug use places the elderly at an increased risk of adverse drug reactions (ADRs), drug interactions, reduced compliance, and increased hospitalizations. Most ADRs are dose-related and are not a result of aging per se. Many patients demonstrate an age-related decline in drug elimination, which necessitates a corresponding reduction in drug dosage if drug accumulation is to be avoided.

A significant level of inappropriate prescribing for the elderly exists, encompassing overuse or polypharmacy, inappropriate use, and underuse. Various assessment tools using explicit and implicit criteria have been developed to evaluate prescribing practices, and several methods have been employed in an attempt to improve suboptimal prescribing. Determining the appropriate starting dose in geriatric patients is a complex task, and guidance is lacking for several drugs that are commonly used in the elderly. Published data support using lower than standard recommended doses for several agents.

**Conclusions.** Substantial opportunities for improvement still exist with regard to geriatric pharmacotherapy. Efforts to address this issue must focus on educating health care providers, improving adherence to prescribed drug regimens, and reducing the financial barriers to access to essential medications. The role of the primary care physician remains central to this process. There are insufficient numbers of trained scientists and physicians to conduct research, deliver services, and teach other health care providers how to treat the elderly wisely.

### RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy and directives at the 2002 AMA Annual Meeting:

1. The Food and Drug Administration should encourage manufacturers to develop low dose formulations of medications commonly used by older patients in order to meet the special needs of this group; require geriatric-relevant labeling for over-the-counter medications; provide incentives to pharmaceutical manufacturers to better study medication effects in the frail elderly and oldest-old in pre- and post-marketing clinical trials; and establish mechanisms for data collection, monitoring, and analysis of medication-related problems by age group. (Policy)
2. The AMA supports increased training in geriatric pharmacotherapy at the medical student and residency level for all relevant specialties and encourage the Accreditation Council for Graduate Medical Education and the appropriate Residency Review Committees to find ways to incorporate geriatric pharmacotherapy into their current programs. (Policy)

3. The AMA will consider convening a task force of relevant specialty societies and other stakeholders to study ways to improve physicians' understanding of geriatric pharmacology and to educate physicians on the special pharmacological needs of the geriatric population. Physicians must have a readily accessible source of current and complete dose response information to individualize drug therapy and minimize the risks of adverse drug reactions. (Directive)

## Generic Drugs (CSA Rep. 6, A-02)

### Summary

**Objectives.** To analyze several issues relevant to the approval and clinical use of generic drugs since passage of the Drug Price Competition and Patent Term Restoration Act of 1984 (commonly referred to as the Hatch-Waxman Act) and to create a resource document for any legislative or regulatory efforts deemed advisable by the American Medical Association (AMA) that may be related to the availability and/or interchangeability of multisource drug products.

**Methods.** Literature searches were conducted in the MEDLINE database for English-language articles published between 1992 and February 2002 using the search terms *drugs, generic* in combination with *therapeutic equivalency, human, drug approval, health care costs, drug monitoring, and pharmacokinetics*. Searches were also conducted for articles published between 1984 and February 2002 using the terms *generic substitution or therapeutic equivalency*, excluding the terms *drug utilization, pharmacy and therapeutic committee, decision making, formularies, hospital, and dose-response relationship*. A total of 783 articles were retrieved for analysis. Articles on therapeutic alternates, patents or other legal issues, or involving generic drugs not approved for marketing in the United States were excluded, leaving 253 articles that were reviewed for information pertinent to this report. Additional references were culled from the bibliographies of these references.

**Results.** The process for generic drug approval has evolved along with changes in federal drug law and regulations. Passage of the Hatch-Waxman Act both encouraged the development of new innovator drugs by extending patent rights and established procedures facilitating the approval of low-cost generic drugs. Concerns about implementation of the Act were raised by the generic drug scandal of 1989, after which the Food and Drug Administration (FDA) reorganized its generic drug operations division. Generic drugs accounted for approximately 42% of all prescriptions at the retail level in the year 2000, but consumed only 8% of the \$141 billion spent on prescription drugs. Currently, the FDA uses an average bioequivalence approach to assure interchangeability. A recent guidance offered by the agency allows a sponsor the option of using another criterion, such as individual bioequivalence. Products that are designated as therapeutically equivalent are designated with an "A" rating in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the "Orange Book"). Although numerous case reports have noted problems temporally related to generic switches for an "A"-rated product, the FDA has been unable to document therapeutic failures attributable to such switches. Nevertheless, physicians remain concerned about therapeutic equivalence, especially for drugs with a narrow therapeutic index.

**Conclusions.** The approval of generic drug products was greatly facilitated by passage of the Hatch-Waxman Act. However, the criteria used by the FDA to ensure bioequivalence among multisource products are widely misunderstood. In practice the mean difference in pharmacokinetic parameters for most generic products is in the range of 3% to 4%. While case reports continue to appear questioning the therapeutic equivalence of selected generic products, a large volume of data supports the safety of generic substitution. The FDA continues to take steps designed to improve the process of bioequivalence testing, including consideration of measures of intrasubject variability that may allow for a better understanding of the general applicability of bioequivalence testing results.

## RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 2002 AMA Annual Meeting:

The 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 (ie, products with potential or known bioequivalence problems) should be prohibited by law, except when there is prior authorization from the prescribing physician.
4. That AMA Policy H-115.974 is reaffirmed. This policy states, in part, that when a physician desires to prescribe a brand name drug, he or she do so by designating the brand name drug product and the phrase "Do Not Substitute" (or comparable phrase or designation, as required by state law or regulation) on the prescription. Every state has a mechanism by which the physician can prevent generic substitution.
5. 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.
6. The FDA, in conjunction with the 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.
7. 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).
8. The Congress should provide adequate resources to the FDA to continue to support an effective generic drug approval process.

## **AMA Endorsement of Screening Standards or Tests (CSA Rep. 6, A-02)**

### **Summary**

**Objective.** To recommend a process for dealing with resolutions submitted to the House of Delegates (HOD) that pertain to endorsement, adoption, or evaluation of, or reimbursement for, specific screening tests and procedures.

**Methods:** Literature searches were conducted in the MEDLINE database for English-language articles published between 1985 and February 2002 using the search term *mass screening or preventive medicine* in combination with *methods, standards, predictive value of tests, sensitivity and specificity, and human*. Articles were selected to provide information on generally accepted principles of screening, the criteria of effective screening tests, and variables that may confound assessment of such tests. In addition, the American Medical Association (AMA) Policy Database was searched using the terms *screen, screening, or reimbursement* to identify relevant policies related to AMA endorsement of screening tests or their reimbursement.

**Results:** Organizations or specialty societies may promote screening guidelines for which sufficient supporting evidence is lacking. Frequently, these organizations rely on consensus panels to develop recommendations. Such guidelines may reflect the personal biases of the participants, and may conflict with or not be supported by the available data.

Like many medical decisions, the decision to use a screening test requires weighing of quantitative information surrounding the test itself, and consideration of the risks and benefits of screening outcomes, as well as qualitative factors, such as individual patients' values and preferences. The extent to which a particular screening test (and program) satisfies key criteria for validity should govern its place in medical practice. Screening tests should meet the minimal criteria of effectiveness based on an evidence-based framework. Formal AMA positions and statements regarding the appropriate use of screening tests should rely on the same approach. Accordingly, evidence, not practice patterns, should be the major arbiter of clinical use and reimbursement recommendations. Current policy advocates that screening tests that are being considered for inclusion in public or private sector insurance products must have evidence-based data to demonstrate improved outcome or quality of life and the cost-effectiveness of the service (Policy H-425.997).

**Conclusions:** New HOD policy is proposed on how resolutions addressing screening issues should be viewed and acted on by the AMA.

### **RECOMMENDATIONS**

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 2002 AMA Annual Meeting:

The AMA believes that:

1. Delegates, state, or specialty societies submitting a resolution seeking endorsement or AMA adoption of specific screening tests must also submit an evidence-based review that determines the strength or quality of the evidence supporting their request, and that evaluates the degree to which the test satisfies the minimal criteria for validating the appropriateness of the screening test, which are: (a) the test must be able to detect the target condition earlier than without screening and with sufficient accuracy to avoid producing large numbers of false-positive and false-negative results; and (b) screening for and treating persons with early disease should improve the likelihood of favorable

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health outcomes compared with treating patients when they present with signs or symptoms of disease.

2. This review will be made available to the reference committee, which will either recommend to the House of Delegates that the resolution be referred to the Council on Scientific Affairs for further study and report back, or not be adopted.