2001 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.*

2001 AMA Annual Meeting

Summaries and Recommendations of Council on Scientific Affairs Reports

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Pharmaceutical Expiration Dates (CSA Rep. 1, A-01)

SUMMARY

Objective. To evaluate the issue of drug expiration dates and the clinical and fiscal consequences of setting such dates.

Methods. Letters sent to the Food and Drug Administration (FDA), the United States Pharmacopeia (USP), and the Pharmaceutical Research and Manufacturers of America (PhRMA) elicited information on how expiration dates are determined for pharmaceutical products, whether the actual shelf life of many drug products exceeds the posted expiration date, and whether data exist on the clinical or fiscal impact of expiration dates. In addition, literature searches were conducted in the MEDLINE and HealthSTAR databases, and the Web sites of the FDA, USP, PhRMA and Defenselink were searched for information.

Data Synthesis. 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.

Based on the Shelf-Life Extension Program (SLEP), a stability testing program the FDA has administered for the United States military, the actual shelf lives of some drug products may be longer than their labeled expiration dates. The Department of Defense has reportedly saved substantial money as the result of extending pharmaceutical expiration dates.

Currently, there are no reliable data on the clinical or fiscal impact of pharmaceutical expiration dates in the civilian environment. PhRMA has informed the American Medical Association (AMA) that lengthening expiration dating for drug products in the civilian environment would not provide the same economic benefits that SLEP has provided to the military; that additional stability testing would add substantial costs to drug development and manufacturing; that most innovator drug products that are close to expiration can be returned to the manufacturer for credit; and that, whereas the military stores its drug products under optimal conditions, this would be far less likely in the civilian environment.

Once the manufacturer's container is opened and drug product is transferred to another container for dispensing or repackaging, the expiration date no longer applies. The USP has developed recommendations for pharmacists to place a "beyond-use" date on the label of the new container. There is little scientific basis for "beyond-use" dates. However, the American Pharmaceutical

Association (APhA) encourages, and 17 states require, that pharmacists place a "beyond-use" date on the label of the prescription container that is dispensed to the patient.

Conclusions. The Council on Scientific Affairs recommends that AMA Policy H-115.983 (AMA Policy Database) be modified.

RECOMMENDATION

The following statement, recommended by the Council on Scientific Affairs, was adopted by the AMA House of Delegates as AMA Policy at the 2001 AMA Interim Meeting:

> AMA Policy H-115.983 Expiration Dates and Beyond-Use Dates of Prescription Drugs Products is amended to read:
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> The 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 to patients and, if this is the case, to conduct longer stability testing on their drug products; (3) (a) 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 beyond-use dates for repackaged products.

Safe Disposal of Syringes, Needles, and Other Sharps in the Community (CSA Rep. 2, A-01)

SUMMARY

Objective. To identify and discuss the public health implications of improper sharps disposal in the community and to summarize current efforts to promote the safe community disposal of used sharps.

Data Sources. Information for this report was derived primarily from the "Safe Community Syringe Disposal: Understanding the Barriers and Creating Solutions" meeting, held on January 29-30, 2001, that was co-sponsored by the American Medical Association (AMA), the Centers for Disease Control and Prevention (CDC), the American Association of Diabetes Educators (AADE), the American Pharmaceutical Association (APhA), and the Academy for Educational Development (AED).

Results. The improper disposal of used sharps is an important public health hazard. Populations exposed to the hazards posed by improperly disposed sharps in the community include children, sanitation workers, waste management employees, hospitality services providers, 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 a bloodborne pathogen. However, there are no defined regulations or laws that guide the disposal of sharps in the community. While states may have their own system for handling the community disposal of used sharps, many are not successful and guidelines that do exist are conflicting and often inappropriate. This has led to confusion among stakeholders regarding the proper disposal of used sharps in the community.

Conclusions. The fact-finding meeting, "Safe Community Syringe Disposal: Understanding the Barriers and Creating Solutions," brought together key individuals with knowledge of the major subject areas and representatives from professional associations, industry, and public health to: (1) identify and discuss major barriers to safe disposal of used sharps in community settings (ie, not health care facilities); (2) formulate strategies for improving options for safe community disposal of used sharps; and (3) develop an action plan for developing practical recommendations to improve safe sharps disposal options at the community level. The problem is complex, requiring multi-layered solutions focused at local levels. Barriers are many, including issues of cost, confidentiality, convenience, lack of leadership, bias, the federal ban on funding of syringe-exchange programs, drug paraphernalia laws, and lack of public awareness. Definitive data are lacking on several issues surrounding community sharps disposal, such as the incidence of injuries sustained by workers in the community (hospitality staff, sanitation workers, etc), the current guidelines and regulations at the state and local level, and the proper disposal of used sharps in the community (eg, in the municipal waste stream, or reclassified as special waste). There is a critical need for an appropriate safe disposal guideline for self-injectors who continue to deposit used sharps in the solid waste system. A problem-identification statement must be developed that can be released to the news media and the public to increase awareness of the problem. A coalition has been established to address this public health problem and the AMA should remain involved in its activities.

RECOMMENDATIONS

The following statement, recommended by the Council on Scientific Affairs, was adopted as AMA Policy at the 2001 AMA Annual Meeting:

> The AMA recognizes that used sharps in the community pose a public health hazard in diverse ways to workers and to the public.

The following statements, recommended by the Council on Scientific Affairs, were adopted as AMA Directives at the 2001 AMA Annual Meeting:

> The AMA supports action at the national, state, and local levels of government in collaboration with the solid waste industry, sharps and pharmaceutical manufacturers, and pharmaceutical distributors and appropriate health care organizations, including local, state and medical specialty societies, to identify, develop, implement, and evaluate strategies to ensure safe sharps disposal in the community.
> The AMA will continue to maintain an active presence in national efforts to develop solutions to the problem of safe sharps disposal in the community.
> A report on the AMA's ongoing activities on this issue will be prepared for the Annual 2002 meeting of the AMA House of Delegates. [Editor's Note: See Safe Disposal of Used Needles and Syringes in the Community: Update on AMA Activities (A-02) (Full Text)]

Update of Activities of the Clinical Research Council (CSA Rep. 3, A-01)

SUMMARY

The Clinical Research Roundtable (CRR) brought together individuals from the academic health community, federal agencies sponsoring and regulating clinical research, private sector sponsors of clinical research, foundations, public and private sector insurance programs, health plans and insurance companies, corporate purchasers of health care, and representatives of patient interests to discuss the challenges facing clinical research and the approaches that might be followed to create a more supporting environment for a broad agenda of high-quality clinical research. This report describes the background/development of the CCR, as well as its mission, current accomplishments, dissemination and outreach activities, and future goals.

RECOMMENDATIONS

Because this is an information report, there are no Recommendations.

Update: Medical Preparedness for Terrorism and Other Disasters (CSA Rep. 4, A-01)

SUMMARY

The AMA's policies on medical preparedness for terrorism and other disasters anticipated the needs identified by national expert panels, and have drawn the attention of one of the most prominent. One of the unique aspects of the AMA recommendations is the proposed use of the Federation of Medicine. As explained in CSA Report 11 (I-00), the Federation provides a ready vehicle for drawing expertise from component societies and for disseminating model curricula and plans. Given the interest in the AMA's recommendations, the CSA believes the AMA should work with and through the Federation to develop a mechanism for coordinating disaster/terrorism planning and response activities that involve more than one component society. These mechanisms can be employed as national planning and preparedness progress.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA Directives at the 2001 AMA Annual Meeting:

> The AMA will work with the Advisory Panel to Assess Domestic Response Capabilities for Terrorism Involving Weapons of Mass Destruction, the Joint Commission on the Accreditation of Healthcare Organizations, and other appropriate parties to promote our policies and recommendations for medical preparedness for terrorism and other disasters.
> The AMA will work with and through the Federation of Medicine to develop a mechanism for coordinating disaster/terrorism planning and response activities that involve more than one component medical society.

Gene Patenting: Utility Examination Guidelines (CSA Rep. 5, A-01)

SUMMARY

On January 5, 2001, the United States Patent and Trademark Office (PTO) published revised guidelines to be used by their personnel in reviewing patent applications for compliance with the "utility" requirement of 35 U.S.C.101. The final guidelines reflect consideration of significant public comment received from 17 organizations and 35 individuals. The majority of the comments were in support of the three utility criteria set forth in the guidelines: specific, substantial, and credible.

The PTO supported strengthening the utility requirements of gene-related patent applications, which is consistent with AMA policy. Continued monitoring of the impact of patenting on access to genetic testing and improved health outcomes remains of crucial importance. With the publication of the draft of the human genome, and the finding that there are fewer genes than originally postulated, it is even more important that the AMA continue to monitor this area for its potential to enhance understanding of the biology of human health.

RECOMMENDATIONS

Because this is an informational report, there are no Recommendations.

Medical Marijuana (CSA Rep. 6, A-01)

SUMMARY

Objective. To review the legal, regulatory, and scientific developments related to the use of marijuana for medical purposes that have occurred since the Council on Scientific Affairs' (CSA) previous report on this subject, CSA Report 10, I-97 [Full Text].

Methods. Literature searches conducted in the MEDLINE, AIDSLINE, and Nexis databases for articles published between 1997 and April 2001 yielded 345 articles for analysis. Articles cited in this report were selected based on provision of information on the function of endogenous cannabinoid systems or the clinical pharmacologic effects of cannabinoid agents. Additional references were culled from the bibliographies of these pertinent references.

Data Synthesis. Four main issues comprise the debate on medical marijuana: (1) its role as a significant drug of abuse and the reluctance of policy makers to dissociate the potential harmful effects of recreational marijuana use from its potential therapeutic effects; (2) the wisdom of burning and inhaling the combustion products of a dried plant product as a valid therapeutic agent; (3) the view that smoked marijuana is not a unique therapeutic substance but rather represents an alternate, but more toxic delivery vehicle for delta-9-tetrahydrocannabinol (THC; Dronabinol®); and (4) the value of analyzing smoked marijuana's potential medical use in the traditional manner of risk versus benefit in individual patients.

Since CSA Report 10 (I-97) was written, there has been substantial progress in further elucidating the role of endogenous cannabinoid systems but little high-quality clinical research into the potential medical utility of marijuana. Nonmedical use of marijuana continues to be problematic in society, and chronic marijuana use is associated with development of tolerance to some of its effects and the appearance of withdrawal symptoms with the onset of abstinence.

Conclusions. Further study is merited on the potential use of marijuana for HIV-infected patients with cachexia, neuropathy, or chronic pain, or who are suffering adverse effects from medication, such as nausea, vomiting, and peripheral neuropathy, that impede compliance with antiretroviral therapy; patients undergoing chemotherapy, especially those being treated for mucositis, nausea, and anorexia, and those patients who do not obtain adequate relief from either acute or delayed emetic episodes from standard therapy; patients suffering from spasticity or pain due to spinal cord injury, or neuropathic or central pain syndromes; and patients with chronic pain and insomnia or to potentiate the analgesic effects of opioids and to reduce their emetic effects in the treatment of postoperative, traumatic, or cancer pain.

RECOMMENDATION

The following statement, recommended by the Council on Scientific Affairs, was adopted by the AMA House of Delegates as AMA Policy at the 2001 AMA Annual Meeting:

> AMA Policy H-95.952, Medical Marijuana is amended to read:
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> (1) The AMA calls for further adequate and well-controlled studies of marijuana and related cannabinoids in patients who have serious conditions for which preclinical, anecdotal, or controlled evidence suggests possible efficacy and the application of such results to the understanding and treatment of disease. (2) the AMA recommends that marijuana be retained in Schedule I of the Controlled Substances Act pending the outcome of such studies. (3) The AMA urges the National Institutes of Health (NIH) to implement administrative procedures to facilitate grant applications and the conduct of well-designed clinical research into the medical utility of marijuana. This effort should include: a) disseminating specific information for researchers on the development of safeguards for marijuana clinical research protocols and the development of a model

informed consent on marijuana for institutional review board evaluation; b) sufficient funding to support such clinical research and access for qualified investigators to adequate supplies of marijuana for clinical research purposes; c) confirming that marijuana of various and consistent strengths and/or placebo will be supplied by the National Institute on Drug Abuse to investigators registered with the Drug Enforcement Agency who are conducting bona fide clinical research studies that receive Food and Drug Administration approval, regardless of whether or not the NIH is the primary source of grant support. (4) The AMA believes that the NIH should use its resources and influence to support the development of a smoke-free inhaled delivery system for marijuana or delta-9-tetrahydrocannabinol (THC) to reduce the health hazards associated with the combustion and inhalation of marijuana. (5) The AMA believes that effective patient care requires the free and unfettered exchange of information on treatment alternatives and that discussion of these alternatives between physicians and patients should not subject either party to criminal sanctions