## 2000 Interim Meeting of the American Medical Association

### Reports of the Council on Scientific Affairs

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Domestic Violence Information and Movie Theaters (CSA Rep. 1, I-00)

SUMMARY

At the 1999 Interim Meeting, the House of Delegates adopted Resolution 419, which called upon the American Medical Association (AMA) to study the Baltimore County Medical Association's (BCMA) experience in developing a public service announcement (PSA) on domestic violence for screening in movie theaters. The Council on Scientific Affairs (CSA) has provided this informational report to facilitate efforts by other interested parties to duplicate this effort.

Conclusion

The CSA believes that the BCMA and the Montgomery County Medical Society have found a reasonably priced mechanism to reach large numbers of people. Their programs stand a good chance of helping patients, and both societies should be congratulated for their innovative and proactive efforts on behalf of patients.

RECOMMENDATIONS

Because this is an informational report, it does not contain recommendations.
Preventing Assault and Rape of Inmates by Custodial Staff (CSA Rep. 2, I-00)

SUMMARY

Resolution 404 (I-99), introduced by the Medical Student Section and referred to the Board of Trustees, asked the American Medical Association (AMA) to:

1. Urge health care professionals working in prisons to be aware of the growing problem of custodial assault and sexual misconduct, and report it to the proper authorities without requiring the inmate to report it him/herself to alleviate guard retaliation; and
2. Urge all states to create statues providing legal protection for inmates against custodial molestation and abuse.

Although inmates are at risk for sexual abuse and assault from both inmates and staff, this report addresses only the latter.

Conclusions

Although the extent of sexual misconduct of inmates in prisons by staff is unknown, the problem is recognized by the Federal Bureau of Prisons, agencies directing state prisons, state legislators, inmates, and advocacy groups. Over the past four years preventive interventions have been implemented in most state systems. Procedures and protocols are defined that direct the management of allegations and for providing medical and psychological services. Although physicians may identify abuse among inmates prior to their filing a grievance, it appears that physicians' major role is in medical evaluation and treatment.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted as Directives at the 2000 AMA Interim Meeting.

1. The AMA urges that all states have legislation that protects prisoners from sexual misconduct and assault.
2. The AMA will urge physicians who work within prisons to ensure procedures are followed for preventing sexual misconduct and assault of prisoners by staff and appropriately managing prisoners if abuse or assault does occur; the investigation of sexual misconduct should be confidential with information disclosed only to those individuals involved in the process.
Reprocessing of Single-use Medical Devices (CSA Rep. 3, I-00)

SUMMARY

Objective. To assess the scientific data and regulatory and legislative actions pertaining to the reprocessing of single-use medical devices via a review of the scientific literature and current media reports.

Data Sources. Literature searches in the MEDLINE database for articles published between 1990 to 1999 using the search term single-use device qualified with the terms reprocessing, or recycling, or safety. Lexis/Nexis news databases were searched for current developments using the search strategy single-use medical devices AND reprocessing. The World Wide Web was searched for information using the search strategy single-use medical devices AND reprocessing.

Data Extraction. The search criteria yielded a combined total of 498 references. One hundred and sixty-seven English-language references contained information relevant to the safety, efficacy and regulation of reprocessing of single-use devices (SUDs) and were examined further. Additional references were culled from the bibliographies of these pertinent references.

Results. Reprocessing of single-use medical devices has occurred since the late 1970s when electrode catheters were reprocessed. There are no scientific data indicating that the proper reprocessing of specific SUDs results in increased risk to the patient. However, there are certain complex SUDs that are difficult to clean and reprocess and therefore should be regulated more closely. Additionally, there are no consensus guidelines for the reprocessing of certain SUDs, and where guidelines exist, there have been instances when they were not followed. Thus, it is appropriate that the Food and Drug Administration (FDA) examine its regulation of the reprocessing industry. The new FDA enforcement guidance released on August 2, 2000, provides a satisfactory framework for increased regulation of the reprocessing of SUDs but must continue to evolve based on the emergence of new data on the safety of reprocessed devices. Further research to provide this data is critical. Regulation by the FDA is the preferred approach to ensure the continued safety of reprocessed SUDs; congressional legislation on this matter is inappropriate and untimely.

Conclusions. The FDA enforcement guidance on the reprocessing of single-use medical devices is an important first step to ensuring the safety and efficacy of reprocessed SUDs. However, the FDA must continue to revise the guidance as new data on the safety and efficacy of reprocessed SUDs emerge. Regulatory action by the FDA is more appropriate than legislative action by Congress to ensure the continued safety of reprocessed single-use medical devices. Increased research is needed to determine characteristics of SUDs that make them safe for reprocessing and to determine better methods of reprocessing. There is a need for device-specific consensus standards for the reuse of SUDs and for properly researched, scientifically validated reprocessing guidelines. Appropriate dissemination of such reprocessing guidelines and adherence to these guidelines by reprocessors is necessary. Medical device failures, especially that of SUDs, should be properly reported to the FDA so that surveillance of adverse events can be improved. These data will enhance the safety of the reprocessing of such devices (if the failure was due to reprocessing) and will also serve to determine whether reprocessing of specific SUDs increases the risk to the patient.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA Policy at the 2000 AMA Interim Meeting.
1. The AMA supports the Food and Drug Administration (FDA) guidance titled "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals" that was issued on August 2, 2000.
2. The AMA supports the development of device-specific standards for the reuse and reprocessing of single-use medical devices involving all appropriate medical and professional organizations and the medical device industry.
3. The AMA encourages increased research by the appropriate organizations and federal agencies into the safety and efficacy of reprocessed single-use medical devices.
4. The AMA supports the proper reporting of all medical device failures to the FDA so that surveillance of adverse events can be improved.

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as directives the 2000 AMA Interim Meeting.

1. The AMA urges the FDA to continue to revise the guidance as new data on the safety and efficacy of reprocessed single-use devices emerge.
2. The AMA urges Congress that the FDA should be given an ample period of time to determine the outcomes of its enforcement guidance on single-use device reprocessing before legislative regulation is considered.
Women’s Health: Sex- and Gender-based Differences in Health and Disease
(CSA Rep. 4, I-00)

SUMMARY

Objective. To review and highlight some of the significant sex- and gender-based differences in health and disease, particularly as they pertain to women's health.

Data Sources. Literature searches were conducted in the MEDLINE database and Lexis/Nexis GenMed library for articles published between 1985 and September 2000 using the terms sex characteristics and health, disease, or epidemiology. Secondary searches were conducted for articles between 1995 and September 2000 using the search term sex factors combined with alcohol, anxiety disorders, arrhythmia, asthma, autoimmune diseases, cardiovascular diseases, congestive heart failure, diabetes, eating disorders, gastrointestinal diseases, hepatic diseases, hypertension, human immunodeficiency virus, lung diseases, menopause, mood disorders, myocardial infarction, osteoporosis, thyroid diseases, schizophrenia, smoking cessation, substance-related disorders, and urologic disorders. References containing information relevant to sex- or gender-based differences in health and disease were examined further. Additional references were culled from the bibliographies of these pertinent references.

Data Synthesis. A working template highlighting some significant findings relevant to sex- and gender-based differences in health and disease was created and offered to several national specialty societies, the Office of Women's Health, and Office of Women's Health Research, the Society for Women's Health Research, the National Women's Health Network, the American Medical Women's Association, and the Women's Physician Caucus for review and comment. Comments that were received were considered in constructing the final draft.

Conclusion. Advances have been made in providing a firmer evidence base on which to establish treatment decisions in women. A requirement for sex-based analysis of clinical research where feasible should be standard. Cardiovascular diseases, lung cancer, and colorectal cancer remain areas where significant opportunities exist for improved prevention in women. The treatment of menopause with respect to the risks and benefits of hormone replacement therapy, including prevention of cardiovascular disease and osteoporosis, requires clarification. Efforts should be intensified to mitigate the use of alcohol and tobacco products by women, particularly younger women, and to gather relevant information on gender-based treatment for these and other substance abuse disorders. Risks for disease also promise to become increasingly important.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 2000 AMA Interim Meeting:

1. The AMA supports the recent trend of increased research on women's health and participation of women in clinical trials, the results of which will permit development of evidence-based prevention and treatment strategies for all women from diverse cultural and ethnic groups, geographic locations, and socioeconomic status.

2. The AMA recommends that all medical/scientific journal editors require, where appropriate, a sex-based analysis of data, even if such comparisons are negative.

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as directives at the 2000 AMA Interim Meeting:
1. The AMA commends the various federal agencies and medical association and women's health organizations that are providing valuable and credible physician/patient education on sex- and gender-based differences in health and disease.

2. The AMA encourages the Women Physicians Congress in its efforts to serve as a clearinghouse for organization resources and related information on sex- and gender-based differences in health and disease, including the use of various forums, such as the AMA Web site and Medem, to provide comprehensive and timely physician education resources on sex- and gender-based differences in health and disease.

3. The AMA will widely distribute this report to the Federation of Medicine, Association of American Medical Colleges.
Classification of Data on Race and Ethnicity (CSA Rep. 5, I-00)

SUMMARY

Objective. This report fulfills Recommendation 7 of Council on Scientific Affairs Report 11 (A-98), "Race and Ethnicity as Variables in Medical Research," requesting that the American Medical Association (AMA) monitor developments in the field of racial and ethnic classification.

Methods. A review of the literature for the years 1980 to 2000 was conducted as part of an ongoing investigation on the use and interpretation of race and ethnicity in medicine. Journal articles were identified through systematic searches of the MEDLINE database. Other sources included the Illinois Bibliographic Information Services, an online collection of databases that includes PsychINFO and the Social Sciences Index. English-language articles were selected based on their ability to provide information on (1) the definition of race and ethnicity; (2) the classification or measurement of race and ethnicity; and (3) the use and interpretation of race and ethnicity as variables in medical research.

Results. The occurrence of many diseases, injuries, and other public health problems is disproportionately higher among some racial and ethnic minorities in the United States. Because of these differences, the collection of data on race and ethnicity has become an important element in patient care as well as public health surveillance designed to monitor differences in health status and access to care. The social construction of current definitions of race and ethnicity, however, presents a number of challenges to public health surveillance and medicine. Specifically, there remains a need to identify a credible classification system for data on race and ethnicity. The Office of Management and Budget (OMB) Directive 15 provides an influential set of guidelines for the collection of data on race and ethnicity. The minimum OMB standard designates five "racial" groups (white, black or African American, Asian, Native Hawaiian or Other Pacific Islander, and American Indian or Alaska Native) and one "ethnic" category (Hispanic or Latino). The revised guidelines also permit multiple racial identification in an attempt to capture the growing diversity of the U.S. population. Recently, the Centers for Disease Control and Prevention and the Agency for Toxic Substances and Disease Registry (CDC/ATSDR) Health Information and Surveillance Board have expanded the utility of the OMB guidelines by developing an expanded classification system based on the original OMB categories.

Conclusion. Until genetic reference data or gene markers are used to calculate the probability of an individual falling into one or more genetically defined population groups, medical researchers are forced to acknowledge the social characteristics of racial and ethnic identification and classification. Within these limitations, the expanded OMB classification system presents a number of advantages to researchers attempting to understand the causal pathways that explain why race and ethnicity are often markers for adverse health risks and outcomes.

RECOMMENDATION

The following statement, recommended by the Council on Scientific Affairs, was adopted by the AMA House of Delegates as AMA policy at the 2000 AMA Interim Meeting:

AMA Policy H-350.983 is amended to read as follows:

The 1997 revised Office of Management and Budget guidelines should be used for the collection of data on race and ethnicity until more scientifically rigorous standards are available. Common Data Elements, as specified by the Standards and Liaison Committee of the Health Information and Surveillance Systems Board, should be used if greater specificity in coding is required.
Accuracy, Importance, and Application of Data from the U.S. Vital Statistics System
(CSA Rep. 6, I-00)

SUMMARY

Objective: This report examines the medical uses and accuracy of data from the US vital statistics system and the role of physicians in the completion of vital records.

Methods: A systematic review of the literature was conducted using the MEDLINE database for the years 1980 to 2000. Other sources included the National Center for Health Statistics (NCHS) and the Illinois Bibliographic Information Services, a collection of databases that includes the Social Sciences Index. English-language articles were selected based on their ability to (1) provide examples of the application of vital statistics to medical research; (2) inform as to the accuracy of data on vital events; and (3) illustrate the role of the physician in the completion of state certificates of birth, death, and fetal death. Further relevant articles and books were selected from the reference listings of the primary journal articles.

Results: Because of its uniformity and comprehensiveness, the national vital statistics system is the primary source of health-related information comparable at the local, state, and national levels. This comparability has made it an invaluable resource for monitoring injury and disease and for the formation of health policy and program planning and evaluation. Physicians play key roles in the completion of US vital records. However, despite the importance of vital statistics data, numerous authors have raised questions regarding the accuracy of data on vital records. A lack of understanding of the information requested, situations in which the most knowledgeable person is not required to complete the certificate, and a reluctance to make certain diagnoses all contribute to problems in accuracy. While training and information dissemination will play important roles in improving the quality of data, arguably the greatest promise for US vital statistics lies in the shift from a paper-based to an electronic process for the recording of vital events.

Conclusion: For the broad purposes of identifying major health problems, direction setting, and program design and evaluation, vital statistics are probably the best available source of information. The role played by physicians in the recording of vital events has far-reaching implications for improving the reliability and accuracy of data on US vital records. Efforts should be pursued to improve accuracy and completeness of data on vital events, including education of medical students and house staff in postgraduate medical training programs, incorporation of questions on the reporting of vital events into medical and specialty board examinations, and training and feedback to practicing physicians. Physicians have also been instrumental in recent revisions to US Standard Certificates of birth, death, and report of fetal death.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA Policy at the 2000 AMA Interim Meeting:

1. AMA Policy H-85.996 is amended to read as follows: The AMA (a) acknowledges that the reporting of vital events is an integral part of patient care; (b) urges physicians to ensure completion of all state vital records carefully and thoroughly with special attention to the use of standard nomenclature; and (c) supports notifying state medical societies and state departments of vital statistics of this policy and encouraging their assistance and cooperation in implementing it.

2. The AMA supports the integration into undergraduate, graduate, and continuing medical education of instruction on the use and proper completion of vital records of birth, fetal death, and death. The presence and effectiveness of this education could be monitored
through the Liaison Committee on Medical Education (LCME) annual questionnaire to medical schools, the joint AMA/Association of American Medical Colleges survey of residency programs, questions on the United States Medical Licensing Examinations, and questions on certifying examinations in the individual specialties.

3. The AMA encourages physicians to provide complete and accurate information on prenatal care and hospital patient records of the mother and infant, as this information is the basis for the health and medical information on birth certificates.

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as Directives at the 2000 AMA Interim Meeting:

1. The AMA, in cooperation with state and local medical societies, encourage states to adopt the changes recommended in the latest revision of the US Standard Certificates of Live Birth, Death, and Report of Fetal Death, planned for implementation in January 2003.

2. The AMA will assist the National Center for Health Statistics (NCHS) and others in making physicians aware of impending changes to the US Standard Certificates, such as the addition of the question on tobacco-related mortality to the medical certification of death.

3. The AMA urges state and specialty medical societies to pursue local policies and/or legislative changes that would enhance the accuracy of vital records in the United States.

4. The AMA will work with the NCHS, the American College of Obstetrics and Gynecology (ACOG), the American Academy of Family Physicians (AAFP), and the American Academy of Pediatrics (AAP) to develop guidelines for physician responsibility in the medical certification of live birth and fetal death.

5. The AMA, in association with state and local medical societies, recommends that state departments of vital statistics adopt uniform policies that ensure the confidentiality of health and medical information on certificates of live birth, fetal death, and death, with consideration given to anticipated guidelines for the electronic transfer of data.

6. The AMA recommends that states work quickly to adopt electronic registration of vital events to enable detailed instructions, help screens, and real-time edit checking as a means to improve the accuracy and timeliness of data on US vital records.

7. The AMA will notify state and local medical societies, state departments of vital statistics, and the NCHS of its policies concerning revised vital records.
AMA Data on Violence Between Intimates (CSA Rep. 7, I-00)

SUMMARY

Objective: To examine data sources on intimate partner violence, same-sex partners violence, elder abuse, child maltreatment, and the relationship between alcohol and family violence, in response to referred Resolution 410 (I-99). The report is not intended to be a thorough review of this vast literature but rather a concise summary of recent research in order to assess the currency of existing AMA policy.

Data Sources: The MEDLINE database was searched using relevant sets of key words for English-language articles published in the past 5 years. In addition, knowledgeable experts were consulted to recommend studies providing national statistics. Where possible, national data were preferred over regional or local studies.

Findings: Data clearly indicate that victimization by intimates and within families continues to be a serious health concern in this country, resulting in several million victimizations annually. This is true despite the fact that some types of such violence are declining. In particular, it appears that incidents of intimate partner violence have declined over the past decade (and possibly longer), and child maltreatment is apparently declining. At the same time, the incidence of elder abuse shows no signs of decline, and it is probably increasing. Although most victims will not be seen by a physician for the injuries suffered in a particular incident, many will be seen by a physician at some point, and physicians have a clear ethical responsibility to address the needs of these patients.

Conclusions: AMA policy accurately reflects the situation likely to be encountered by most physicians, but the CSA believes that the numerous policy statements should be consolidated into a single, more coherent statement. No new policy is recommended.

RECOMMENDATION

The following statement, recommended by the Council on Scientific Affairs, was adopted by the AMA House of Delegates as AMA Policy at the 2000 AMA Interim Meeting:

Policy - Family and Intimate Partner Violence

The American Medical Association believes that all forms of family and intimate partner violence are major public health issues and urges the profession, both individually and collectively, to work with other interested parties to prevent such violence and to address the needs of victims. Physicians have a major role in lessening the prevalence, scope and severity of child maltreatment, intimate partner violence, and elder abuse, all of which fall under the rubric of family violence. To support physicians in practice, the AMA will continue to campaign against family violence and remains open to working with all interested parties to address violence in US society. The AMA's efforts will be guided, in part, by its Advisory Council on Family Violence.

1. The AMA believes that all physicians should be trained in issues of family and intimate partner violence through undergraduate and graduate medical education as well as continuing professional development. The AMA, working with state, county and specialty medical societies as well as academic medical centers and other appropriate groups such as the Association of American Medical Colleges, should develop and disseminate model curricula on violence for incorporation into undergraduate and graduate medical education, and all parties should work for the rapid distribution and adoption of such curricula when developed. These curricula should include coverage of the diagnosis,
treatment, and reporting of child maltreatment, intimate partner violence, and elder abuse and provide training on interviewing techniques, risk assessment, safety planning, and procedures for linking with resources to assist victims. The AMA supports the inclusion of questions on family violence issues on licensure and certification tests.

2. The prevalence of family violence is sufficiently high and its ongoing character is such that physicians, particularly physicians providing primary care, will encounter victims on a regular basis. Persons in clinical settings are more likely to have experienced intimate partner and family violence than non-clinical populations. Thus, to improve clinical services as well as the public health, the AMA encourages physicians to: (a) Routinely inquire about the family violence histories of their patients as this knowledge is essential for effective diagnosis and care; (b) Upon identifying patients currently experiencing abuse or threats from intimates, assess and discuss safety issues with the patient before he or she leaves the office, working with the patient to develop a safety or exit plan for use in an emergency situation and making appropriate referrals to address intervention and safety needs as a matter of course; (c) After diagnosing a violence-related problem, refer patients to appropriate medical or health care professionals and/or community-based trauma-specific resources as soon as possible; (d) Have written lists of resources available for victims of violence, providing information on such matters as emergency shelter, medical assistance, mental health services, protective services and legal aid; (e) Screen patients for psychiatric sequelae of violence and make appropriate referrals for these conditions upon identifying a history of family or other interpersonal violence; (f) Become aware of local resources and referral sources that have expertise in dealing with trauma from victimization; (g) Be alert to men presenting with injuries suffered as a result of intimate violence because these men may require intervention as either victims or abusers themselves; (h) Give due validation to the experience of victimization and of observed symptomatology as possible sequelae; (i) Record a patient’s victimization history, observed traumatized potentially linked to the victimization, and referrals made; (j) Become involved in appropriate local programs designed to prevent violence and its effects at the community level.

3. Within the larger community, the AMA: (a) Urges hospitals, community mental health agencies, and other helping professions to develop appropriate interventions for all victims of intimate violence. Such interventions might include individual and group counseling efforts, support groups, and shelters. (b) Believes it is critically important that programs be available for victims and perpetrators of intimate violence. (c) Believes that state and county medical societies should convene or join state and local health departments, criminal justice and social service agencies, and local school boards to collaborate in the development and support of violence control and prevention activities.

4. With respect to issues of reporting, the AMA strongly supports mandatory reporting of suspected or actual child maltreatment and urges state societies to support legislation mandating physician reporting of elderly abuse in states where such legislation does not currently exist. At the same time, the AMA opposes the adoption of mandatory reporting laws for physicians treating competent, non-elderly adult victims of intimate partner violence if the required reports identify victims. Such laws violate basic tenets of medical ethics. If and where mandatory reporting statutes dealing with competent adults are adopted, the AMA believes the laws must incorporate provisions that (a) do not require the inclusion of victims’ identities; (b) allow competent adult victims to opt out of the reporting system if identifiers are required; (c) provide that reports be made to public health agencies for surveillance purposes only; (d) contain a sunset mechanism; and (e) evaluate the efficacy of those laws. State societies are encouraged to ensure that all mandatory reporting laws contain adequate protections for the reporting physician and to educate physicians on the particulars of the laws in their states.

5. Substance abuse and family violence are clearly connected. For this reason, the AMA believes that: (a) Given the association between alcohol and family violence, physicians should be alert for the presence of one behavior given a diagnosis of the other. Thus, a physician with patients with alcohol problems should screen for family violence, while physicians with patients presenting with problems of physical or sexual abuse should
screen for alcohol use. (b) Physicians should avoid the assumption that if they treat the problem of alcohol or substance use and abuse they also will be treating and possibly preventing family violence. (c) Physicians should be alert to the association, especially among female patients, between current alcohol or drug problems and a history of physical, emotional, or sexual abuse. The association is strong enough to warrant complete screening for past or present physical, emotional, or sexual abuse among patients who present with alcohol or drug problems. (d) Physicians should be informed about the possible pharmacological link between amphetamine use and human violent behavior. The suggestive evidence about barbiturates and amphetamines and violence should be followed up with more research on the possible causal connection between these drugs and violent behavior. (e) The notion that alcohol and controlled drugs cause violent behavior is pervasive among physicians and other health care providers. Training programs for physicians should be developed that are based on empirical data and sound theoretical formulations about the relationships among alcohol, drug use, and violence.
Xenotransplantation: Scientific Implications (CSA Rep. 8, I-00)

SUMMARY

Objective. To determine the medical risks and benefits essential to the formation of effective policy guiding clinical uses of xenotransplantation (see I-00 Council on Ethical and Judicial Affairs report, "The Ethical Implications of Xenotransplantation").

Methods. Literature searches in the MEDLINE database for articles published between 1990 to 2000 using the search terms xenotransplantation qualified with the terms public health, or infectious disease, or clinical trials yielded a combined total of 264 references. One hundred and thirty-eight English-language references contained information directly related to the public health, ethical, and clinical trials aspects of xenotransplantation and were examined further. Additional references were culled from the bibliographies of those references deemed relevant. Lexis/Nexis news databases were searched for current developments using the search strategies xenotransplantation AND clinical trials or xenotransplantation AND public health.

Data Synthesis. Xenotransplantation is defined by the Public Health Service to include any procedure that involves the transplantation, implantation, or infusion into a human recipient of either (a) live cells, tissues, or organs from a nonhuman animal source or (b) human body fluids, cells, tissues, or organs that have had ex vivo contact with live nonhuman animal cells, tissues, or organs. Potential public health risks are posed by xenografts, and ethical issues (which are addressed in detail in the CEJA report) surround the subject. Commentary from a variety of reports written by a number of the major stakeholders including the Food and Drug Administration (FDA), the Institute of Medicine, the World Health Organization, the US Department of Health and Human Services, and others are discussed.

Conclusions. Before xenotransplantation can be realized, a number of public health as well as ethical issues must be further discussed, and it must be determined how to develop a larger body of research on the safety and efficacy of clinical trials. Once this information has been gathered xenografts may become more common to potentially treat a range of human disorders. The Council on Scientific Affairs (CSA) recommends that the American Medical Association (AMA) support the general xenotransplantation guidelines produced in 2000 by the Public Health Service, the 1999 FDA guidelines relating to nonhuman primates and xenotransplantation, the 1999 FDA guidelines on measures to reduce the possible risk of transmission of zoonoses from xenotransplantation, and the Institute of Medicine xenotransplantation guideline document. Further, the CSA recommends that the AMA support the Secretary of the Department of Health and Human Services’ Advisory Committee on Xenotransplantation (SACX) to encourage public discussion and education on the unique issues associated with the topic. Further recommendations include that the AMA encourage continuation of research on xenotransplantation to gather data to determine more accurate risk analysis and that the AMA monitor the development of guideline documents produced by the major stakeholders, and revisit the issue in the future as the research becomes more clinically relevant.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as Directives at the 2000 AMA Interim Meeting:

1. The AMA supports the general xenotransplantation guideline documents produced in 2000 by the Public Health Service, the 1999 Food and Drug Administration (FDA) guidelines relating to nonhuman primates and xenotransplantation, the 1999 FDA guidelines on measures to reduce the possible risk of transmission of zoonoses from
xenotransplantation, and the Institute of Medicine xenotransplantation guideline document.

2. The AMA supports the Secretary of the Department of Health and Human Services' Advisory Committee on Xenotransplantation (SACX) to encourage public discussion and education on the unique issues associated with the topic.

3. The AMA encourages continuation of research on xenotransplantation to gather data to determine more accurate risk analysis.

4. The AMA will monitor the development of guideline documents produced by the major stakeholders, and revisit the issue in the future as the research becomes more clinically relevant.
Patenting of Genes and Their Mutations (CSA Rep. 9, I-00)

SUMMARY

Resolution 510, introduced by the American College of Medical Genetics and the College of American Pathologists and adopted at the 2000 American Medical Association (AMA) Annual Meeting, asked: "That the AMA examine the issues surrounding gene patenting and report to the House of Delegates at the 2000 Interim Meeting." This report discusses the current status of gene patenting, changes proposed by the US Patent and Trademark Office (PTO) Revised Utility Examination Guidelines, and the current controversy between the biotechnology industry and the biomedical community.

Methods: The report reflects extensive discussions with representatives of industry and specialty societies, as well as review of Council on Ethical and Judicial Affairs (CEJA) Report 2, "Patenting the Human Genome" (I-97), and the June 2000 proceedings of the Department of Health and Human Services (DHHS) Secretary's Advisory Committee on Genetic Testing. In addition, MEDLINE and BIOETHICSLINE (National Library of Medicine databases) were searched using the terms gene and patent.

Conclusion

Many of the controversies about current patent law reflect broader issues of health care policy--in particular, the issues of license agreements that inhibit use, too greatly increase the cost, or inhibit research on the patented gene--and are therefore not the purview of the PTO. However, the requirement of the patent application to demonstrate utility; the biomedical community's concern about the low threshold to meet that requirement; and the potential impact of inhibiting the full exploration of patented genes that might occur later through subsequent clinical application, which is of concern to maintain a high quality of medical care, are issues that must be addressed. Informal survey data that demonstrate the withdrawal of genetic testing by university-based laboratories need further study.

RECOMMENDATIONS

The following statement, recommended by the Council on Scientific Affairs, was adopted by the AMA House of Delegates as AMA policy at the 2000 AMA Interim Meeting:

1. AMA Policy H-140.944 is amended to read as follows:
   AMA policy on gene patents is: (1) Patents on processes--for example, processes used to isolate and purify gene sequences, genes and proteins, or vehicles of gene therapy--do not raise the same ethical problems as patents on the substances themselves and are thus preferable. (2) Substance patents on purified proteins present fewer ethical problems than patents on genes or DNA sequences and are thus preferable. (3) The AMA: (a) supports the concept of gene patents only if the inventor has demonstrated a practical, real world, specific and substantial use (credible utility) for the sequence; (b) supports equitable access to licenses or sublicenses of gene patents for diagnostic genetic tests to any Clinical Laboratory Improvement Act (CLIA)-certified laboratory at a reasonable royalty; (c) supports the concept of gene patents only if the inventor has demonstrated a practical use beyond merely being a tool for scientific discovery; (d) recommends that the Department of Health and Human Services (DHHS) Secretary's Advisory Committee on Genetic Testing consider the development of special guidelines for the licensing of human gene-related patents as a way of promoting research and other benefits; (e) encourages the DHHS as part of its regulatory oversight of genetic testing to continue monitoring the impact of gene patenting and licensing agreements on access to relevant medical care; and (f) encourages the DHHS Secretary's
Advisory Committee on Genetic Testing to further discuss what "credible utility" should refer to within the field of biotechnology. (4) One of the goals of genetic research is to achieve better medical treatments and technologies. Granting patent protection should not hinder this goal. Individuals or entities holding patents on genetic material should not allow patents to languish and should negotiate and structure licensing agreements in such a way as to encourage the development of better medical technology.

The following statement, recommended by the Council on Scientific Affairs, was adopted by the AMA House of Delegates as a directive at the 2000 AMA Interim Meeting.

The Council on Scientific Affairs will continue to monitor progress in the area of patenting of genes and their mutations and report back to the House of Delegates as appropriate.
Genetically Modified Crops and Foods (CSA Rep. 10, I-00)

SUMMARY

Objective. To review the technology used to produce transgenic crops and examine issues relevant to the utilization of transgenic crops and genetically modified foods, including the current regulatory framework, possible human health effects, potential environmental impacts, and other consumer-related issues.

Data Sources. Eleven reports issued over the last 2 years by various scientific and governmental bodies on selected aspects of genetically modified crops were reviewed. Additionally, literature searches were conducted in the MEDLINE database and Lexis/Nexis GenMed library for articles between 1990 and September 2000 using the terms genetic engineering combined with food microbiology; food technology, agriculture; plants, edible; food; and crops, agricultural. A secondary search was conducted for articles between 1995 and September 2000 using the search term plants, transgenic. References containing information relevant to the safety, regulation, and environmental impact of transgenic crops and foods were examined further. Additional references were culled from the bibliographies of these pertinent references. The World Wide Web was searched for information using the search terms genetically modified foods or genetically modified crops, revealing several links to additional scientific and regulatory sites.

Results. More than 40 transgenic crop varieties have been cleared through the federal review process with enhanced agronomic and/or nutritional characteristics or one or more features of pest protection (insect and viruses) and tolerance to herbicides. The most widely used transgenic pest-protected plants express insecticidal proteins derived from the bacterium Bacillus thuringiensis (Bt). Crops and foods produced using recombinant DNA techniques have been available for fewer than 10 years and no long-term effects have been detected to date. These foods are substantially equivalent to their conventional counterparts. Genetic engineering is capable of introducing allergens into recipient plants, but the overall risks of introducing an allergen into the food supply are believed to be similar to or less than that associated with conventional breeding methods. The risk of horizontal gene transfer from plants to environmental bacteria or from plant products consumed as food to gut microorganisms or human cells is generally acknowledged to be negligible, but one that cannot be completely discounted. Pest-resistance due to exposure to Bt-containing plants has not occurred to date, and harmful effects on nontarget organisms, which have been detected in the laboratory, have not been observed in the field. Nevertheless, these and other possible environmental effects remain areas of concern.

Conclusions. Federal regulatory oversight of agricultural biotechnology should be science-based. Methods to assure the safety of foods derived from genetically modified crops should continue to be refined and improved. Although no untoward effects have been detected, the use of antibiotic markers that encode resistance to clinically important antibiotics should be avoided if possible. Genetic modification of plants could potentially lead to detrimental consequences to the environment. Therefore, a broad-based plan to study environmental issues should be instituted. There is no scientific justification for special labeling of genetically modified foods, as a class, and voluntary labeling is without value unless it is accompanied by focused consumer education. Government, industry, and the scientific and medical communities have a responsibility to educate the public and improve the availability of unbiased information on genetically modified crops and research activities.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as AMA policy at the 2000 Interim AMA Meeting:
1. The AMA recognizes the continuing validity of the three major conclusions contained in the 1987 National Academy of Sciences white paper "Introduction of Recombinant DNA-Engineered Organisms into the Environment."

2. Federal regulatory oversight of agricultural biotechnology should continue to be science-based and guided by the characteristics of the plant, its intended use, and the environment into which it is to be introduced, not by the method used to produce it, in order to facilitate comprehensive, efficient regulatory review of new genetically modified crops and foods.

3. The AMA believes that as of December 2000, there is no scientific justification for special labeling of genetically modified foods, as a class, and that voluntary labeling is without value unless it is accompanied by focused consumer education.

4. The AMA supports efforts for the systematic safety assessment of genetically modified foods and encourage: (a) development and validation of additional techniques for the detection and/or assessment of unintended effects; (b) continued use of methods to detect substantive changes in nutrient or toxicant levels in genetically modified foods as part of a substantial equivalence evaluation; (c) development and use of alternative transformation technologies to avoid utilization of antibiotic resistance markers that code for clinically relevant antibiotics, where feasible; and (d) that priority should be given to basic research in food allergenicity to support the development of improved methods for identifying potential allergens.

5. The AMA supports continued research into the potential consequences to the environment of genetically modified crops including the: (a) assessment of the impacts of pest-protected crops on nontarget organisms compared to impacts of standard agricultural methods, through rigorous field evaluations; (b) assessment of gene flow and its potential consequences including key factors that regulate weed populations; rates at which pest resistance genes from the crop would be likely to spread among weed and wild populations; and the impact of novel resistance traits on weed abundance; (c) implementation of resistance management practices and continued monitoring of their effectiveness; and (d) development of monitoring programs to assess ecological impacts of pest-protected crops that may not be apparent from the results of field tests.

6. The AMA recognizes the many potential benefits offered by genetically modified crops and foods, not support a moratorium on planting genetically modified crops, and encourages ongoing research developments in food biotechnology.

7. The AMA recognizes that the government, industry, and the scientific and medical communities have a responsibility to educate the public and improve the availability of unbiased information on genetically modified crops and of research activities.

The following statement, recommended by the Council on Scientific Affairs, was adopted as a directive at the 2000 Interim AMA Meeting:

The AMA will monitor the forthcoming final rule for plant pesticides from the Environmental Protection Agency and respond as appropriate.
Medical Preparedness for Terrorism and Other Disasters (CSA Rep. 11, I-00)

SUMMARY

Objective. To identify preparedness and response issues for physicians and county, state, and national medical societies in dealing with acts of terrorism and other disasters. The report is not intended as a comprehensive review of public health, federal, and military activities, although many of these are mentioned. Rather, it focuses on the need for involvement of community physicians and their medical societies.

Methods. This report and its recommendations are based in part on presentations and discussions that occurred on April 3-6, 2000, at Medic WMD 2000, a conference about weapons of terrorism and the military assets that could respond to an act of terrorism. Participants included representatives from state and county medical societies, national medical specialty societies, public health organizations, military health services, and federal health agencies. Additional information was obtained from a MEDLINE review of recent peer-reviewed articles, and from discussions with representatives of relevant federal agencies and other organizations.

Data Synthesis. Physicians will play critical roles in the response to disasters, whether due to terrorism or unintentional or natural causes. Acts of terrorism or disasters may involve biological agents, toxic chemicals, conventional explosives, or exposure to nuclear or radiological agents. Most of the necessary skills and knowledge for physicians are extensions of the working tools they use daily, such as forming a differential diagnosis for an infectious process or caring for acute trauma patients. However, preparedness planning and education for individual physicians will vary depending on practice specialty and setting. Overall preparedness for disasters can be enhanced by collaboration with local and state health departments; continuing medical education (CME) programs for physicians; physician participation in disaster care planning by health care facilities, including ensuring adequate equipment and procedures; and coordination with community resources, such as fire and police departments, emergency medical technicians, utilities, schools, government officials, and large employers. Local, county, and state medical societies can help facilitate community disaster planning, which includes physician call-up systems, coordination of medical care at standard and emergency care sites, plans for receiving and integrating state and federal medical aid (including health care workers) dispatched to the community, and public information. Specialty medical societies are especially well-positioned to provide relevant CME programs and activities and, as opinion leaders, to impress on their members the importance of the subject. The American Medical Association is best suited to act as liaison with national associations (eg, the Association of State and Territorial Health Officials, the National Association of City and County Health Officials) and federal agencies (eg, the Office of Emergency Preparedness, the Centers for Disease Control and Prevention, the Food and Drug Administration, and the Department of Defense) involved in response planning and to help form connections between those agencies and state and specialty medical societies.

Conclusions. Responding to acts of terrorism or natural disasters will require the coordinated efforts of physicians, public health agencies, health care facilities, and community, state, and federal agencies. Local, state, and specialty medical societies and the AMA can play crucial roles in preparing the medical community to deal with the challenges presented by such disasters.

RECOMMENDATIONS

The following statements, recommended by the Council on Scientific Affairs, were adopted by the AMA House of Delegates as Directives at the 2000 AMA Interim Meeting:

1. The AMA calls for the creation of a public-private entity (including federal, military, and public health content experts) that will collaborate with medical educators and medical
specialty societies to: (a) develop audience-specific medical education curricula on
disaster medicine and the medical response to terrorism, with a first charge to develop
curricula on bioterrorism, and disseminate these to medical students, physicians in
training, and physicians in practice; (b) develop information resources on disaster
medicine and the medical response to terrorism for civilian physicians and other health
care workers; (c) encourage and work with state and specialty societies, the Centers for
Disease Control and Prevention, the Office for Emergency Preparedness, the Agency for
Healthcare Research and Quality, the pharmaceutical industry, and other appropriate
federal, military and private organizations to develop model plans for community medical
response to disasters, including terrorism; and (d) address the issue of reliable, timely,
and adequate reporting of dangerous diseases by community physicians to public health
authorities. The AMA will report back to the House of Delegates on the status of this
public-private entity as appropriate.

2. The AMA encourages the Federation of Medicine to become involved in planning for the
medical component of responses to disasters, including terrorism, at levels appropriate to
the Federation component: (a) county/local medical societies and organized medical
staffs are encouraged to become involved in local public health and community planning
and physician education; (b) state societies are encouraged to become involved in state
response planning and physician education; and (c) specialty societies are encouraged to
take the lead in conducting and encouraging education of their members in essential
components of disaster medicine, as well as encouraging their members to participate in
local response planning.

3. The AMA encourages the JCAHO and state licensing authorities to include the evaluation
of hospital plans for terrorism and other disasters as part of the periodic accreditation and
licensure visits by their representatives.