

REPORTS OF THE COUNCIL ON SCIENCE AND PUBLIC HEALTH

The following reports, 1–9, were presented by Sandra A. Fryhofer, MD, Chair:

1. CSAPH SUNSET REVIEW OF 2003 HOUSE POLICIES

Reference committee hearing: see report of [Reference Committee D](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

At its 1984 Interim Meeting, the House of Delegates (HOD) established a sunset mechanism for House policies (Policy G-600.110). Under this mechanism, a policy established by the House ceases to be viable after 10 years unless action is taken by the House to retain it.

The objective of the sunset mechanism is to help ensure that the AMA Policy Database is current, coherent, and relevant. By eliminating outmoded, duplicative, and inconsistent policies, the sunset mechanism contributes to the ability of the AMA to communicate and promote its policy positions. It also contributes to the efficiency and effectiveness of House of Delegates deliberations.

At its 2012 Annual Meeting, the House modified Policy G-600.110 to change the process through which the policy sunset review is conducted. The process now includes the following:

(1) As the House of Delegates adopts policies, a maximum ten-year time horizon shall exist. A policy will typically sunset after ten years unless action is taken by the House of Delegates to retain it. Any action of our AMA House that reaffirms or amends an existing policy position shall reset the sunset “clock,” making the reaffirmed or amended policy viable for another 10 years. (2) In the implementation and ongoing operation of our AMA policy sunset mechanism, the following procedures shall be followed: (a) Each year, the Speakers shall provide a list of policies that are subject to review under the policy sunset mechanism; (b) Such policies shall be assigned to the appropriate AMA Councils for review; (c) Each AMA council that has been asked to review policies shall develop and submit a report to the House of Delegates identifying policies that are scheduled to sunset. (d) For each policy under review, the reviewing council can recommend one of the following actions: (i) Retain the policy; (ii) Sunset the policy; (iii) Retain part of the policy; or (iv) Reconcile the policy with more recent and like policy; (e) For each recommendation that it makes to retain a policy in any fashion, the reviewing Council shall provide a succinct, but cogent justification. (f) The Speakers shall determine the best way for the House of Delegates to handle the sunset reports. (3) Nothing in this policy shall prohibit a report to the HOD or resolution to sunset a policy earlier than its 10-year horizon if it is no longer relevant, has been superseded by a more current policy, or has been accomplished. (4) The AMA Councils and the House of Delegates should conform to the following guidelines for sunset: (a) when a policy is no longer relevant or necessary; (b) when a policy or directive has been accomplished; or (c) when the policy or directive is part of an established AMA practice that is transparent to the House and codified elsewhere such as the AMA Bylaws or the AMA House of Delegates Reference Manual: Procedures, Policies and Practices. (5) The most recent policy shall be deemed to supersede contradictory past AMA policies. (6) Sunset policies will be retained in the AMA historical archives.

In this report, the Council on Science and Public Health (CSAPH) presents its recommendations on the disposition of the House policies from 2003 that were assigned to it. The CSAPH’s recommendations on policies are presented in the Appendix to this report.

RECOMMENDATION

The Council on Science and Public Health recommends that the House of Delegates policies that are listed in the Appendix to this report be acted upon in the manner indicated in the Appendix and the remainder of this report be filed.

APPENDIX – Recommended Actions on 2003 House Policies and Directives

Policy Number	Title	Recommended Action and Rationale
H-5.983	Pregnancy Termination	Retain in part to read as follows: The AMA adopted the position that pregnancy termination be performed only by appropriately trained physicians (MD or DO) and encourages any specialty society which has adopted a contrary position to review and modify its position to comply with that of the AMA.
H-5.985	Fetal Tissue Research	Retain in part to read as follows: The AMA reaffirms its position in supports of the use of fetal tissue obtained from induced abortion for scientific research.
H-10.966	Prevention of Fires Related to Cigarette Smoking	Retain. Still a viable tobacco control issue being pursued by states.
H-10.980	Motorcycles and Bicycle Helmets	Retain pending future consolidation report.
H-10.981	Prohibition on the Public Sale of Fireworks	Retain in part. Sunset (3) as it is not realistic. (1), (2), (4) and (5) are still relevant.
H-10.994	Maximum Temperature in Water Heaters	Sunset. No longer necessary.
H-10.995	Use of Technology to Prevent Explosions	Retain in part. Sunset (1) as it is not necessary. Retain (2) as it is still relevant.
H-15.954	Older Driver Safety	Retain. Still relevant.
H-15.961	Safety for Passengers in the Back of Pickup Trucks	Retain. Still relevant as some states do not have laws in place.
H-15.963	Daytime Visible Headlights	Sunset. Not necessary.
H-15.964	Police Chases and Chase-Related Injuries	Retain in part. Sunset (1) as it is not necessary. Retain (2) and (3) as they are still relevant.
H-15.966	Preventing Underride Motor Vehicle Crash Injury	Retain. Still relevant.
H-20.900	HIV, Sexual Assault, and Violence	Sunset (1) Not a strategic priority. Retain (2) as it is still relevant.
H-20.902	Sanctions for Willfully Infecting Others with HIV	Sunset. The term “sanctions” is vague. “Knowingly and willingly” constitute criminal conduct.
H-20.903	HIV/AIDS and Substance Abuse	Retain (1), (2), (3), and (4) as they are still relevant. Sunset (5), (6), and (7) as this is not a strategic priority.
H-20.908	Medical Care of HIV-Infected Patients	Sunset. Outdated.
H-20.909	HIV-Infected Aviation Pilots	Sunset. The FAA has solid policies and processes in place now.
H-20.910	HIV-Infected Children	Retain. Still relevant.
H-20.911	Reporting of HIV-and HBV-Infected Physicians	Sunset. Policy not ethically well grounded. FSMB has policy in this area.
H-20.912	Guidance for HIV-Infected Physicians and other Health Care Workers	Sunset. Outdated.
H-20.913	Prevention and Control of HIV and other Bloodborne Pathogens in Health Care Settings	Sunset. Now standard of care.
H-20.914	Discrimination Based on HIV Seropositivity	Retain. Still relevant.
H-20.916	Breastfeeding and HIV Seropositive Women	Retain. Consistent with CDC Guidelines.
H-20.917	Neonatal Screening for HIV Infection	Retain in part to read as follows: Our AMA: (1) Urges the U.S. Public Health Service, other appropriate federal agencies, private researchers, and health care industries to continue to pursue research, development, and implementation of diagnostic tests and procedures for more accurate demonstration of HIV infection in the newborn; and supports the widespread use of such tests in early diagnosis; (2) Favors giving consideration to rapid HIV testing of newborns, with maternal consent, when the maternal HIV status has not been determined during pregnancy or labor; and (3) Supports voluntary, routine HIV testing of neonates in states with a high prevalence of HIV infection with maintenance of strict confidentiality. When treatment modalities with proven benefits for infected neonates are available. Our AMA supports mandatory HIV testing of all newborns in high prevalence areas.

Policy Number	Title	Recommended Action and Rationale
H-20.919	Patient Disclosure of HIV Seropositivity	Retain. Still relevant.
H-20.921	HIV/AIDS to be Considered as a Communicable and a Sexually Transmitted Disease	Sunset. Not necessary.
H-30.951	Boating Under the Influence	Retain in part. Sunset (1) it is not necessary. Retain (2) as it is still relevant.
H-30.955	Sequelae of Alcohol Intake	Sunset. Superseded by H-30.942.
H-30.974	Return to Work Following Successful Rehabilitation for the Disease Alcoholism and Other Chemical Dependencies	Sunset. Not necessary.
H-35.994	Treatment of Persons with Hearing Disorders	Retain. Still relevant.
H-50.975	Safety of Blood Donations and Transfusions	Retain. Still relevant.
H-50.976	Blood Bank Look-Back Programs	Retain. Still relevant.
H-50.977	Blood Donor Recruitment	Retain in part. Modify (1) to read as follows: Our AMA: (1) advocates to the federal government for <u>supports</u> the establishment of a national volunteer blood donor education and recruitment campaign to assure an adequate and readily available blood supply; and
H-50.982	Autologous Blood Transfusions	Retain. Still relevant.
H-55.984	Screening and Treatment for Breast and Cervical Cancer	Retain. Still relevant.
H-60.941	Effects of Alcohol on the Brains of Underage Drinkers	Retain. Still relevant.
H-60.963	Preventable Airway Obstructions in Children	Retain in part to read as follows: The AMA will develop, disseminate, and promote <u>supports</u> educational programs to apprise the public of the dangers of airway obstruction hazards in children and on methods to prevent these hazards.
H-60.966	Recommendations for Ensuring the Health of the Adolescent Athlete	Sunset. Superseded by H-470.971.
H-60.970	Minimizing Iron Poisoning	Sunset. Not necessary.
H-60.975	Political Influence and the American Teenage Study	Retain with change in title to read: "Political Influence and the NIH American Teenage Study
H-75.994	Contraception and Sexually Transmitted Diseases	Retain. Still relevant.
H-85.972	The Compassionate Care of the Terminally Ill	Sunset. Not necessary.
H-90.977	Impairment and Disability Evaluations	Retain. Still relevant.
H-95.948	Research on Drug Abusing Populations	Sunset. Not necessary.
H-95.956	Harm Reduction Through Addiction Treatment	Retain. Still relevant.
H-95.959	Expanding Treatment for the Heroin Addict Population	Sunset. Buprenorphine now available.
H-95.961	Policy on Illegal Drug Use	Retain. Still relevant.
H-95.989	Drug Paraphernalia	Retain. Still relevant.
H-100.976	Benzodiazepine Education	Retain in part. Still highly relevant. Modify policy as follows: Our AMA encourages physicians interested in the true addictive nature of benzodiazepines and their rational use to seek information from appropriate sources, of information such as the American Psychiatric Association's Task Force Report, Benzodiazepine Dependence, Toxicity and Abuse.
H-100.979	Repeal of Offensive Federal Regulations	Retain. Still an issue. Change title to read: Repeal of Offensive Federal Regulations
H-115.989	Protective Packaging	Sunset. No longer relevant.
H-120.960	Protection for Physicians Who Prescribe Pain Medication	Retain. Still relevant.
H-120.971	Emergency Department Administration of Schedule II Drugs Under Physician Order	Sunset. No longer necessary.
H-120.972	Confidentiality of Identification During Prescription Refills	Sunset. Reflects current practices.
H-120.977	Drug Error Issues	Sunset. Superseded by H-120.968.
H-120.993	Physicians' Desk Reference	Sunset. Accomplished.

Policy Number	Title	Recommended Action and Rationale
H-130.992	Proposed Crisis Relocation and Shelter Plans	Retain. Still relevant.
H-130.993	Use of Emergency Medical Information Aids	Retain. Still relevant.
H-135.948	Toxicity of Computers and Electronics Waste	Retain. Still relevant.
H-135.951	Environmental Chemical and Disease Tracking and Reduction	Sunset. Accomplished.
H-135.960	Endorsement of the Concept of Recyclable and Biodegradable Packing, Including Pharmaceutical Packaging	Sunset. No longer necessary.
H-135.961	Risks of a High-Level Radioactive Waste Repository	Retain in part. (1) Sunset-No longer relevant, (2) Retain-Still relevant, (3) Modify to read as follows: urges the U.S. Congress to continue the process it has set in place to characterize <u>establish</u> a site for a high-level radioactive waste repository; and (4) Sunset-Not a strategic priority.
H-135.962	Management of Waste Associated with Health Care Delivery	Sunset. Accomplished.
H-145.987	Funding for Hunter Safety Education Programs and Wildlife Restoration	Sunset. Not a realistic goal.
H-145.988	AMA Campaign to Reduce Firearm Deaths	Retain in part to read as follows: The AMA as part of its campaign against violence, will publicize information to educate <u>supports educating</u> the public regarding methods to reduce death and injury due to keeping guns, ammunition and other explosives in the home.
H-150.951	Dietary Supplements Containing Ephedra Alkaloids	Sunset. Accomplished.
H-150.964	Availability of Heart-Healthy and Health-Promoting Foods at AMA Functions	Retain. Still relevant.
H-150.966	FDA Regulations Regarding the Inclusion of Added L-Glutamic Acid Content on Food Labels	Retain. Still an issue.
H-170.965	Education on Condom Use	Retain in part. Still relevant. (5) Sunset-Not a strategic priority.
H-170.966	Human Sexuality Education	Retain. Still relevant.
H-170.967	Rehabilitative Programs, Mental Health, and Educational Services for Girls in the Juvenile Detention System	Retain. Still relevant.
H-175.988	Thermography Update	Sunset. Some recognized diagnostic use exists.
H-215.978	Guns in Hospitals	Retain in part. Change name JCAHO to The JC in (1)
H-220.940	Changing Joint Commission on Accreditation of Healthcare Organization Standards and Agenda for Change	Rescind. No longer relevant.
H-220.942	Joint Commission Accreditation of Provider Networks	Rescind. No longer relevant.
H-220.945	Economic Credentialing	Rescind. Superseded by H-230.971. Also included in AMA Physician's Guide to Medical Staff Organization Bylaws.
H-220.946	Unreasonable Burden of Joint Commission on Accreditation of Healthcare Organizations Standards and Surveys	Retain in part to read as follows: The AMA requests the JCAHO <u>The Joint Commission</u> to study and consider the ability of small hospitals, particularly in rural areas, to bear the burden of the increasing demands on staff and financial resources in the implementation of the current and proposed standards; and urges the JCAHO <u>The Joint Commission</u> to eliminate standards that increase health care costs without demonstrably improving the quality of care. Change title as follows: Unreasonable Burden of <u>The Joint Commission on Accreditation of Healthcare Organizations</u> Standards and Surveys
H-220.949	JCAHO	Rescind. No longer relevant.
H-225.968	Standard Admitting Orders	Retain. Still relevant.
H-245.983	Baby Walkers	Retain. Still relevant.
H-245.985	Mandatory Labeling for Waterbeds and Beanbag Furniture	Retain in part. Change word "petitions" to "urges."

Policy Number	Title	Recommended Action and Rationale
H-260.972	SI Units of Measure	Sunset. Not necessary.
H-365.996	Regulation of Occupational Carcinogens	Retain. Still relevant.
H-370.976	Regulating Human Tissue Industry	Sunset. Not necessary.
H-420.991	Fetal Effects of Maternal Alcohol Use	Retain. Still relevant.
H-425.994	Medical Evaluations of Healthy Persons	Retain. Still relevant.
H-430.988	Prevention and Control of HIV/AIDS and Tuberculosis in Correctional Facilities	Retain in part. Modify 1 (a) to read as follows: Federal and state correctional systems should provide comprehensive medical management for all entrants, which includes mandatory <u>voluntary</u> testing for HIV infection and <u>mandatory testing</u> for tuberculosis followed by appropriate treatment for those infected; Rescind (d) as too difficult to implement. Rescind (e) as already covered in (a). Modify (g) to read as follows: During their post-test counseling procedures, HIV-infected inmates prison medical directors should be encouraged to confidentially notify their sexual or needle-sharing partners. Modify (h) to read: Correctional medical care must, as a minimum, meet the prevailing standards of care for HIV-infected persons in the outside community at large. Prisoners should have access to all -approved therapeutic drugs and generally employed treatment strategies. Reletter as appropriate, and remainder of policy still relevant.
H-430.989	Disease Prevention and Health Promotion in Correctional Facilities	Modify in part. Modify (b) to read as follows: (b) an increase in direct referral by correctional systems of parolees with a <u>recent, active</u> history of intravenous drug use to drug treatment centers. Remainder of policy still relevant.
H-440.888	Public Health Leadership	Retain. Still relevant.
H-440.931	Update on Tuberculosis	Retain in part. Delete (1) as implementation is problematic. Modify (2) as follows: All prison inmates should be tuberculin skin-tested upon arrival, <u>and</u> annually thereafter. and within 60 days of their release Those who are positive should be managed as medically appropriate and contact tracing performed. Renumber recommendations, and remainder of policy still relevant.
H-440.932	Hepatitis B Vaccine	Sunset per current CDC recommendations.
H-440.934	Adequacy of Sterilization in Commercial Enterprises	Retain in part. Modify to read as follows: The AMA requests that state medical societies explore with their state health departments <u>ensure</u> the adequacy of sterilization of instruments used in commercial enterprises (tattoo parlors, beauty salons, barbers, manicurists, etc.) because of the danger of exchange of infected blood-contaminated fluids.
H-455.980	National Biomedical Tracer Facility	Retain. Supply issue still a concern.
H-455.992	Management of Nuclear and Isotope-Related Injuries and Contamination	Sunset. Not necessary.
H-460.915	Cloning and Stem Cell Research	Retain. Still relevant.
H-460.944	Support for Investigator-Initiated Medical Research	Sunset. Not consistent with current realities.
H-460.946	Support for the National Center for Research Resources of the National Institutes of Health	Sunset. NCRR was dissolved in 2011.
H-460.948	Consumer Product Testing	Sunset. Not necessary.
H-470.972	Medical and Nonmedical Uses of Anabolic-Androgenic Steroids	Retain in part. (1) Still relevant. (2), (3), (4), (5), (6), and (7) Sunset. Not necessary.
H-475.998	Cochlear Implants	Sunset. Not necessary.
H-480.956	Commercialized Medical Screening	Retain. Still relevant.
H-480.966	Multiplex DNA Testing for Genetic Conditions	Retain in part. Sunset (1) as no longer accurate. Modify to read as follows: Policy of the AMA is that: (1) physicians should not routinely order DNA-based tests for multiple genetic

Policy Number	Title	Recommended Action and Rationale
		conditions; (2) tests for more than one genetic condition should be ordered only when clinically relevant and after the patient or parent/guardian has had full counseling and has given informed consent; (2) efforts should be made to educate clinicians and society about the uncertainty surrounding DNA-based genetic testing; and (3) (4) before genetic testing, physicians should counsel patients should be counseled on the familial implications of genetic test results, including and emphasize the importance of sharing results in instances where there is a high likelihood that a relative is at risk of serious harm, and where the relative could benefit from early monitoring or from treatment.
H-480.978	Expected Rise in Cost of Medical Care as a Result of Innovations	Retain in part with change in title to read as follows “ Expected Rise in Cost of Medical Care as a Result of Innovations. ” Still relevant.
H-480.984	Technology Assessment in Medicine	Rescind. Principles covered in H-330.926, H-460.909, H-460.943, and H-480.990.
H-485.995	TV Violence	Retain. Still relevant.
H-515.964	Violence Activities	Retain. Still relevant.
H-515.975	Alcohol, Drugs, and Family Violence	Retain in part. (1), (2), (3) – Retain, still relevant. Sunset (4) and (5) – outdated and/or no longer necessary.
H-515.979	Violence as a Public Health Issue	Retain. Still relevant.
H-515.981	Family Violence-Adolescents as Victims and Perpetrators	Retain in part. Modify (1) (a) to read: Our AMA (1) will use its communications mechanisms to (a) encourages physicians to screen adolescents about a current or prior history of maltreatment. Special attention should be paid to screening adolescents with a history of alcohol and drug misuse, irresponsible sexual behavior, eating disorders, running away, suicidal behaviors, conduct disorders, or psychiatric disorders for prior occurrences of maltreatment; and
D-20.997	Preventing Needlestick Injuries in Health Care Settings	Sunset. Accomplished.
D-55.998	Encourage Appropriate Colorectal Cancer Screening	Retain in part. Modify to read as follows: Our AMA, in conjunction with interested organizations and societies, will promote <u>support</u> educational and public awareness programs to assure that physicians actively encourage their patients to be screened for colon cancer and precursor lesions, and to improve patient awareness of appropriate guidelines, particularly within minority populations for all high risk groups, including all individuals over age 50.
D-60.987	Gender-Specific Rehabilitation Programs, Mental Health and Educational Services for Girls in the Juvenile Detention System	Sunset. Superseded by Policy H-170.967.
D-60.988	Early Childhood and Family Education as a Mechanism to Advance Family Health	Sunset. Superseded by AMA Policy.
D-60.989	Effects of Alcohol on the Brains of Underage Drinkers	Retain in Part and Change to Policy reading: Our AMA will consult with relevant specialty societies (whose members provide care for adolescents and young adults) in order to create a supports creating a higher level of awareness about the harmful consequences of underage drinking, and seek to work collaboratively to address the underage drinking problem.
D-95.992	Study of Abuse of Medications Containing Dextromethorphan	Sunset. Accomplished.
D-100.989	Pharmaceutical Shortages	Sunset. Superseded by H-100.956.
D-115.995	Readable Pharmaceutical Drug Inserts and Attachments to Drug Advertisements	Sunset. Accomplished.
D-120.981	Pharmaceutical Assistance Programs	Sunset. Accomplished.
D-120.983	Concerning Pain Management	Sunset. Accomplished.

Policy Number	Title	Recommended Action and Rationale
D-120.985	Increasing Awareness of Opioid Pain Management Treatments	Retain. Still relevant.
D-120.986	Guidance for Physicians on Internet Prescribing	Sunset. Accomplished.
D-130.992	Medical Preparedness for Terrorism and Other Disasters	Sunset. Accomplished.
D-140.978	Commercial Medical Screening	Sunset. Accomplished.
D-145.998	Reauthorization and Strengthening of the 1994 Assault Weapons Ban	Sunset. Outdated.
D-145.999	Epidemiology of Firearm Injuries	Retain (1) and (2). Delete (3) and (4) Accomplished.
D-150.993	Obesity and Culturally Competent Dietary and Nutritional Guidelines	Sunset. Accomplished.
D-150.994	Sympathomimetic Amine-Based Products	Sunset. Accomplished.
D-150.995	Dietary Supplement and Health Education Act	Sunset. Superseded by H-150.954.
D-220.982	AMA Support for Physician Surveyors Consistent with AMA Policy	Sunset. Accomplished.
D-220.983	Provision for Conflict Resolution in Joint Commission Standards	Sunset. Accomplished.
D-220.985	Enforcement of JCAHO Medical Staff Standards	Sunset. Accomplished.
D-225.987	Interference with Medical Staff Participation on Hospital Boards	Sunset. Accomplished.
D-265.995	Physician Testimony Related to Tobacco and Health	Sunset. No longer relevant.
D-370.990	Umbilical Cord Blood Transplantation: The Current Scientific Understanding	Change to Policy. Retain (1) as it is still relevant. Modify (2) as follows: (2) work with appropriate organizations to educate support education for physicians and the public about the potential benefits of, and limitations to, umbilical cord blood transplantation as an alternative to bone marrow transplantation.
D-370.991	Shared Accountability for Increasing Organ and Tissue Donations	Sunset. Accomplished and/or not a strategic priority.
D-405.996	Physician Well-Being and Renewal	Retain. Still relevant.
D-420.997	Pain Relief During Labor & Delivery	Sunset. Standard of care.
D-440.979	Public Health Leadership	Sunset. Accomplished.
D-440.997	Support for Public Health	Retain. Still relevant.
D-460.983	Translating Biomedical Research to the Bedside	Retain (1) and (2) – Still relevant. Sunset (3), (4), and (5) – Accomplished.
D-460.986	Commercialized Medical Screening	Retain in part and Change to Policy reading: Our AMA will urge government funding agencies to continue to fund supports the funding of well-designed, large-scale clinical trials aimed at determining the safety, value, and cost-effectiveness of screening imaging procedures.
D-470.995	Hormone Abuse by Adolescents	Sunset. (1) and (2) Accomplished. (3) Not a strategic priority.
D-480.983	Medical Patents and Their Infringement on the Art of Medicine	Modify as follows and change to Policy: Our AMA will reiterate its supports for the Ganske Compromise and discourages the medical community from soliciting patents on medical methodology.
D-480.989	Multiplex Genetic Testing in Newborns	Sunset. Accomplished.
D-490.983	Annual Tobacco Report 2003	Retain. Still relevant.
D-490.985	Tobacco Products Sold in Businesses that Dispense Medications	Sunset. Accomplished.
D-490.986	Support for U.S. Surgeon General Richard H. Carmona, MD	Sunset. Accomplished.
D-490.987	Federal Interagency Committee on Smoking and Health	Sunset. Accomplished.
D-490.988	Anti-Tobacco Poster Contest	Sunset. Accomplished.
D-490.995	Allocation of Tobacco Settlement Funds	Sunset. No longer relevant.
D-495.999	Tobacco Warning Labels	Sunset. FDA no longer pursuing. Superseded by Policy H-495.989.
D-515.994	Violence Activities	Sunset. Accomplished. Superseded by H-515.993.

2. NANOTECHNOLOGY SAFETY AND REGULATION (RESOLUTION 512-A-12)

Reference committee hearing: see report of [Reference Committee E](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF RESOLUTION 512-A-12 AND REMAINDER OF REPORT FILED

See Policy [H-480.949](#)

INTRODUCTION

Resolution 512-A-12 introduced by the California Delegation and referred by the House of Delegates asked:

That our American Medical Association: (1) recognize both the benefits and the potential risks to public health and the environment from the widespread use of nanoparticles; and (2) endorse responsible regulation of existing or new nanoparticles prior to their introduction in industrial or consumer products, such as, but not limited to, standardized research, toxicologic testing, biomonitoring and product labeling.

Nanotechnology is the science of manipulating matter at the nanoscale (i.e., dimensions of 1-100 nanometers) to create new and unique materials and products. Nanoparticle components are present in materials such as polymers, electronics, paints, batteries, sensors, fuel cells, solar cells, coatings, computers and display systems. Nanoparticles are also found in other consumer products such as cosmetics and pharmaceuticals. Concerns have been raised, suggesting that nanoparticles could have undesirable effects on the environment and unintended effects on human health. Nanomaterials also present challenges to the policy and risk assessment process, in part because no clear answer exists to the question of where they fit within current regulatory and policy guidance and frameworks. This report offers a brief overview of the current uses of nanotechnology, potential effects on human health and the environment, and regulation of nanomaterials. Several comprehensive reports on nanotechnology and its regulation are available as additional resources.¹⁻⁶

METHODS

Literature searches were conducted in the PubMed database for English-language articles using the search terms “nanotechnology,” “nanoparticle,” and “nanomaterial” along with the terms “health” and “environment.” Additionally, a Google search was conducted using the same search terms. Several comprehensive reports on nanotechnology and its regulation were consulted.¹⁻⁶

NANOPARTICLE TECHNOLOGY

As mentioned, nanotechnology is the understanding and control of matter at dimensions of approximately 1-100 nanometers.⁴ For comparison, a sheet of paper is about 100,000 nanometers thick, a human hair is about 80,000 nanometers thick, the protein hemoglobin is about 5.5 nanometers in diameter, and the DNA double helix is about 2.5 nanometers in diameter.^{1,7} Nanoscale materials often have properties that differ from those of conventionally scaled materials.⁸ These differences may include altered magnetic properties, electrical or optical activity, structural integrity, or chemical or biological activity.¹ The altered properties of nanoscale materials are largely due to the increased surface area per mass, which allows a greater amount of the nanoparticle to come in contact with its surroundings and induce reactivity.⁷

Commercial Application of Nanotechnology

Over 800 commercial products and applications of nanoparticle-based materials exist.⁹ Selected examples are:

- nanoscale polymer composites that make baseball bats, tennis rackets, motorcycle helmets, automobile bumpers, luggage, and power tool housings more lightweight, stiff, durable, and resilient;
- surface treatments of fabrics that help to resist wrinkling, staining, and bacterial growth and provide lightweight ballistic energy deflection in personal body armor;

- nanoscale materials in cosmetic products that provide better coverage and absorption, increase antioxidant and antimicrobial properties, and filter UV light;
- nano-engineered materials in automotive products such as high-powered rechargeable battery systems, thermoelectric materials for temperature control, lower-rolling-resistance tires, high-efficiency/low-cost sensors and electronics, thin-film smart solar panels, and fuel additives and improved catalytic converters for cleaner exhaust and extended range;
- nanomaterials in computing, communications, and other electronics applications provide faster, smaller, and more portable systems that can manage and store larger amounts of information; and,
- nanocomposites in food containers minimize carbon dioxide leakage out of carbonated beverages, or reduce oxygen inflow, moisture outflow, or the growth of bacteria to keep food fresh and safe for longer periods of time.

Medical Applications of Nanotechnology

Nanotechnology is being widely applied in many facets of health care.^{9,10} For example, quantum dots (semi-conducting nanocrystals) show unique optical and electronic properties like size-tunable light emission, simultaneous excitation of multiple fluorescence colors, high signal brightness, and long-term photostability. These properties have enhanced both *in vitro* and *in vivo* biological imaging, and are being used to image sentinel lymph nodes, tumor-specific receptors, malignant tumor detectors, and tumor immune responses.¹¹

In oncology, nanoparticulate antineoplastic drugs can better target tumors and reduce the systemic toxicity associated with their conventional counterparts. Liposomal doxorubicin (doxorubicin encapsulated in a liposome) is preferentially directed away from sites at which the non-encapsulated form would cause cardiac and gastrointestinal toxicity, and instead exits the circulation where tumor growth has disrupted capillaries.¹²

In another example, nanoparticle-based hydrogels used as wound dressings have been introduced. Nanoscale inorganic particles have been added to hydrogels as reinforcing agents, improving the strength, elasticity, absorptive capability, and barrier properties of the wound dressing.¹³

NANOPARTICLES AND HUMAN HEALTH

Since humans are routinely exposed to a number of materials containing nanoparticles, concerns exist about how such exposure affects human health. The increased surface-to-volume ratio of nanoparticles creates an increased potential for reactivity, and their small size may facilitate uptake into and between various cells or cell components allowing for transport to other parts of the body. In addition to surface-to-volume ratio and size, the shape, solubility, and surface chemistry of nanoparticles may affect human tissue and cells.^{1,5}

Little is currently known about the long-term effects of exposure to engineered nanoparticles, but cell culture and animal studies have begun to offer clues. Complicating the effort to characterize effects is the number of different nanoparticles and applications, each of which may affect cells differently. Data on the cellular effects of nanoparticles come mostly from *in vitro* cell culture nanotoxicology studies. Interactions between the nanoparticle and the cell can be chemical, including the production of reactive oxygen species, dissolution and release of toxic ions, and disturbance of the electron/ion cell membrane transport activity; or physical, including disruption of membrane integrity and stability, transport processes, protein conformation and folding, and protein aggregation.¹⁴ Intracellularly, some nanoparticles appear to target mitochondria, sometimes affecting function and leading to apoptosis.¹⁴⁻¹⁷ Often, nanoparticles end up in lysosomes, which carry out the cell's digestion and excretion activities, although it is not known whether or how those processes are affected.^{14,18,19} Some nanoparticles are small enough to enter the nuclear space through pores in the nuclear envelope, and have been shown to induce DNA damage.^{14,20,21} At the protein level, the ability of nanoparticles to affect protein folding has been shown to interfere with cell signaling processes and to result in aggregations or amyloid-like structures.^{14,22-24}

In vivo studies are necessary to examine routes of exposure and how cellular effects translate to tissue and organ function in complex multi-cellular organisms like humans. Studies using animal models have demonstrated that the organs most commonly exposed to nanoparticles are the lungs, skin, and gut; nanoparticles gain access to the systemic circulation by inhalation, direct contact, and ingestion, respectively.^{14,25} Transport throughout the body has been demonstrated, though in very small quantities; biodistribution studies have shown low concentrations of nanoparticles in the liver, spleen, heart, brain and central nervous system.¹⁴ It is not yet clear to what extent

nanoparticles bioaccumulate in organs, nor at what rate they are excreted.¹⁴ In tissues exposed to nanoparticles, inflammation has been observed, but the mechanisms resulting in inflammation are unclear.^{14,26}

No known studies to date have examined the effects of real-world exposures in humans, i.e., exposure levels that an average human being would experience in day-to-day life. Cell culture and animal studies have used exposure levels that are thought to be far greater than those experienced by an average person. From current research findings, no evidence exists of adverse changes in human health as a result of the use of nanoparticles currently on the market.²⁷ However, the known adverse health effects of ultrafine particulate matter (dust and pollutants), which is also nanoscale-sized, suggests that the effect of engineered nanoparticles on human health warrants rigorous scientific study.¹⁴

NANOPARTICLES AND THE ENVIRONMENT

In addition to concerns about potential direct human health effects of nanoparticles, concerns exist about the potential of nanomaterials to adversely affect the environment. In free form, nanoparticles can be released in the air or water during production or as a waste byproduct of production, and ultimately accumulate in the soil, water, plant, or animal life. In fixed form, where they are part of a manufactured substance or product, nanoparticles will ultimately have to be recycled or disposed of as waste. Toxicity of nanoparticles to microorganisms, aquatic invertebrates, and some terrestrial organisms has been described,²⁸ but similar to studies on human exposure, it is not known whether the acute experimental exposure levels accurately reflect potential toxicity from real-world exposure levels. Few nanotoxicity studies have been reported for plants.²⁸

A challenge in evaluating risk associated with the manufacture and use of nanomaterials is the diversity and complexity of the types of materials available and being developed, as well as the vast potential uses of nanomaterials.² Improvements in standard protocols for environmental risk assessments are needed and is an area of active study for the Environmental Protection Agency (EPA) and other research groups.^{2,29} While potential nanoparticle hazards are a focus of attention, the use of some nanomaterials has led to the development of new environmental sensors and remediation technologies that may provide new tools for preventing, identifying, and solving environmental problems.²

OVERSIGHT AND REGULATION OF NANOTECHNOLOGY PRODUCTS

Existing statutes and responsibility to protect the health of the public provide a foundation for the FDA's regulation and oversight of nanomaterials. The FDA has not adopted a regulatory definition of "nanomaterial;" instead, it has taken a broadly inclusive approach to considering whether products contain nanomaterials or involve nanotechnology.³⁰ The Agency recently issued a draft guidance for industry suggesting that several factors be considered when determining whether products include nanomaterials or otherwise involve nanotechnology.³¹ For example:

1. Has the product or material been engineered to occur in the nanoscale range (as opposed to naturally occurring in the nanoscale range)?
2. Is one dimension of the product or material less than 100 nanometers?
3. Does the product or material exhibit properties that are attributable to its dimensions?²⁸

The FDA's approach to regulating nanomaterials consists of the following attributes:^{30,32}

- Product-focused and science-based: Assessments take into account the effects of the nanomaterial(s) in the context of each product and its intended use.
- Follows legal standards for different product classes: Food and drug products will be regulated according to their corresponding standards criteria. For example, foods are evaluated for safety, while drugs are evaluated for safety and effectiveness.
- Attention to nanomaterials is incorporated into pre-market review procedures: For products required to undergo premarket review (new drugs, biologics, food additives, color additives, certain devices, and certain new ingredients in dietary supplements), review procedures include attention to whether the use of nanomaterials suggests the need for additional data on safety and effectiveness.
- Consultation when pre-market review authority does not exist: For products not required to undergo pre-market review (most dietary supplements, cosmetics, and food), FDA encourages manufacturers to consult with it

before bringing nanomaterial products to the market. The consultation serves the purpose of reviewing safety information and designing necessary post-marketing oversight.

- Post-market monitoring: FDA will monitor the marketplace for nanomaterial products and will take action as needed to protect consumers.
- Industry responsibility: Regardless of whether or not a product is subject to pre-market review, manufacturers must use all information possible to ensure that their product meets all applicable safety standards.
- Collaboration with domestic and international regulatory counterparts: FDA works with other US agencies⁸ to contribute to and coordinate overarching policy on nanotechnology; and with foreign regulatory counterparts to share information on nanotechnology products.
- Technical advice and guidance: FDA will offer technical advice and guidance to help industry meet its obligations to ensure that nanomaterial products are safe.

The EPA has the obligation and mandate to protect human health and safeguard the environment. Its goal of better understanding and addressing potential risks from exposure to nanoscale materials and products is carried out in a number of its Offices:²

- Office of Pollution Prevention and Toxics: Administers a voluntary program for the evaluation of nanomaterials and reviews nanomaterial premanufacture notifications under the Toxic Substances Control Act.
- Office of Air and Radiation/Office of Transportation and Air Quality: Reviews nanomaterial registration applications.
- Office of Pesticide Programs: Reviews potential nanoscale pesticides for exposure and hazard profiles on a case-by-case basis.
- Office of Solid Waste and Emergency Response: Investigates the use of nanoscale materials for environmental remediation.
- Office of Enforcement and Compliance Assurance: Evaluates existing statutory and regulatory frameworks to determine the enforcement issues associated with nanotechnology.

In 2000, the National Nanotechnology Initiative (NNI) was created as a central point of communication, collaboration, and cooperation for the 26 Federal agencies involved in nanotechnology research and regulatory activities. The mission of the NNI is to expedite the discovery, development and deployment of nanoscale science and technology to serve the public good, through a program of coordinated research and development aligned with the missions of the participating agencies.³³ NNI invests heavily in research projects that examine the safe use of nanomaterials, in turn acting as a resource to the FDA, EPA, and other regulatory agencies.⁴

CONCLUSIONS AND AMA POLICY CONSIDERATIONS

Nanotechnology has demonstrated great benefit in the improvement of consumer products and applications. Very little is known about how nanomaterials affect human health and the environment, but preliminary research has shown that acute exposure to nanoparticles can affect cellular behavior and may be toxic to some components of the environment. More detailed research is needed to examine how real-world exposure levels affect human health and the environment. In the meantime, regulation of products or applications that include nanomaterials will occur on a case-by-case basis, using science-based methods to evaluate the balance of benefits and risks. AMA policy is strongly supportive of the FDA's mission to protect the health of the public, and of the EPA's efforts to ensure that the public is protected from environmental pollution.

RECOMMENDATION

The Council on Science and Public Health recommends that the following statement be adopted in lieu of Resolution 512-A-12, and that the remainder of the report be filed.

Our American Medical Association: (a) recognizes the benefits and potential risks of nanotechnology; (b) supports responsible regulation of nanomaterial products and applications to protect the public's health and the environment; and (c) encourages continued study on the health and environmental effects of exposure to nanomaterials.

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3. IS OBESITY A DISEASE? (RESOLUTION 115-A-12)

Reference committee hearing: see report of [Reference Committee D](#).

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
IN LIEU OF RESOLUTION 115-A-12 AND
REMAINDER OF REPORT FILED**
See Policies [H-150.953](#) and [H-440.866](#)

INTRODUCTION

Resolution 115-A-12, "Obesity Should Be Considered a Chronic Medical Disease State," introduced by the Illinois Delegation at the 2012 American Medical Association (AMA) Annual Meeting and referred by the House of Delegates, asks:

That our AMA: (1) recognize obesity and overweight as a chronic medical condition (de facto disease state) and urgent public health problem; (2) recommend that providers receive appropriate financial support and payment from third-party payers, thus ensuring that providers have an incentive to manage the complex diseases associated with obesity; (3) work with third-party payers and governmental agencies to recognize obesity intervention as an essential medical service; and (4) establish a comprehensive ICD code for medical services to manage and treat obese and overweight patients.

Reference Committee A recommended referral of Resolution 115-A-12 to clarify the first resolve. AMA Policy H-150.953, "Obesity as a Major Public Health Program," already urges improved coding and payment mechanisms for the evaluation and management of obesity (Appendix). Additionally, both the ICD-9-CM and ICD-10-CM contain diagnosis codes for overweight and obesity, as well as body mass index (BMI). Therefore, this report addresses only the first resolve of Resolution 115-A-12.

The Council on Scientific Affairs (CSA) previously addressed this issue.¹ Based on its interpretations of definitions of disease in common use, the Council argued that it was premature to classify obesity as a disease, citing the lack of characteristic signs or symptoms due to obesity, as well as evidence of any true causal relationships between obesity and morbidity and/or mortality. The resultant Policy D-440.971, "Recommendations for Physician and Community Collaboration on the Management of Obesity," recommends that our AMA "work with the Centers for Disease Control and Prevention to convene relevant stakeholders to evaluate the issue of obesity as a disease, using a systematic, evidence-based approach" (Appendix). No formal meeting with the Centers for Disease Control and Prevention (CDC) and other stakeholders was ever held.

This report examines the definitions of obesity and disease, the limitations of those definitions, and arguments both for and against the classification of obesity as a disease. The possible implications for provider reimbursement, public policy, and patient stigma also are considered. Of central interest is the potential impact of classifying obesity as a disease on improving patient care and health outcomes. This report does *not* address food addiction, binge eating disorder, or other psychological disorders that may result in obesity, as the currently prevailing definitions of obesity do not specify its underlying causes.

CURRENT AMA POLICY RELATED TO OBESITY

The AMA has more than 20 policies that specifically refer to obesity. Most do not define or describe the term, but among those that do, obesity is referred to as a: “complex disorder” (Policy H-150.953), “urgent chronic condition” (Policy D-440.971), “epidemic” (Policy D-440.952), and “major health concern” and “major public health problem” (Policy H-440.902). AMA policy does not clearly define obesity as a disease, although policy D-440.980 directed our AMA to convene a task force to “recommend measures to better recognize and treat obesity as a chronic disease” (Appendix).

METHODS

English language reports were selected from searches of the PubMed and Google Scholar databases from 2004 to January 2013 using the search terms “obesity as a disease,” “obesity a disease,” “obesity should be considered a disease,” “what is disease,” and “definition of disease.” Additional articles were identified by manual review of the reference lists of pertinent publications. Websites managed by federal agencies and applicable professional and advocacy organizations also were consulted for relevant information.

BACKGROUND

Opinions within the medical profession have been divided for a number of years on whether or not obesity should be considered a disease, rather than a condition or disease risk factor. Those in favor of classifying obesity as a disease argue that excess body fat, which results from myriad genetic, behavioral, and other environmental factors, impairs a number of normal body functions. While the adverse health consequences and healthcare costs associated with obesity are generally well-recognized even in the absence of a disease label, proponents argue that neither provider reimbursement nor research into effective treatments will be adequate until obesity is considered a disease. Those opposed to classifying obesity as a disease argue that excess body weight increases risk of morbidity and mortality, but does not guarantee it. Concerns also exist about labeling 1/3 of Americans as “ill” and increasing stigmatization of obese individuals. However, others argue that classifying obesity as a disease will actually decrease stigma. These issues, and others, are discussed in more detail below.

WHAT IS OBESITY?

The World Health Organization (WHO) defines overweight and obesity as “abnormal or excessive fat accumulation that may impair health.”² The WHO, as well as the Centers for Disease Control and Prevention (CDC)³ and the National Heart, Lung, and Blood Institute (NHLBI),⁴ describe overweight and obesity in adults using body mass index (BMI) categories (Table 1). The NHLBI additionally recommends measuring waist circumference in adults with BMIs below 35 kg/m², to further assess disease risk.⁴

While Simple and Inexpensive, BMI is a Limited Measure of Body Fatness

Both the WHO and NHLBI guidelines recognize that BMI is an indirect and imperfect measure of body fatness, although more accurate than body weight alone.⁴ Originally designed as a rough population-level indicator of obesity, BMI has been widely recommended as an inexpensive clinical screening tool to help assess disease risk, in addition to other indicators such as blood pressure and blood lipids.⁵ Associations between BMI and adiposity (as well as disease risk, described below) vary by age, gender, ethnicity, socioeconomic status, stature, and athletic training. These variations generally reflect population-specific differences in body composition, fat distribution, causes of overweight, and genetic susceptibility.⁵ As a screening tool for obesity, BMI demonstrates low sensitivity, particularly at BMIs below 30.⁶ For example, some people with BMIs < 25 may have excess adipose tissue and proinflammatory cytokines, as well as metabolic disturbances associated with obesity, such as insulin resistance, hyperinsulinemia, dyslipidemia, hypertension, and cardiovascular disease (CVD).^{5,6} On the other hand, some individuals with BMIs greater than 30 may not have excess body fat; however, even if they do, they may exhibit high insulin sensitivity and normal blood pressure and lipid levels.^{5,6} Due to the limitations of BMI, some argue that BMI should be excluded from the definition of obesity when deciding whether or not obesity is a disease.⁷⁻⁸

NHLBI is currently developing new guidelines on overweight and obesity in adults as part of its development of cardiovascular risk reduction guidelines for adults.⁹ These new guidelines will be based on rigorous and standardized systematic reviews of the scientific literature, which may clarify some of the uncertainties around the assessment

and management of obesity in clinical practice. The release date of the new guidelines is currently unknown, but their availability for public comment is expected later in 2013.

Obesity as Measured by BMI is Associated with Increased Morbidity

Despite the limitations of BMI, a substantial body of literature has found increased BMI to be associated with myriad diseases and conditions, including: type 2 diabetes, coronary heart disease, stroke, hypertension, dyslipidemia, several cancers, gall bladder disease, osteoarthritis, asthma, chronic back pain, sleep apnea, pregnancy complications, stress incontinence, and depression.^{5-6,10} The nature of the relationships between BMI and these conditions is generally similar across population groups, although the specific level of risk at a given BMI often differs by age, gender, ethnicity, and/or socioeconomic status.⁵

The Obesity Paradox

While co-morbidities generally increase as BMI increases, a number of research studies report no effect--or even slightly protective effects--of overweight and obesity on mortality risk (i.e., J- or U-shaped associations).^{5-6,11} A number of factors beyond the inherent limitations of BMI may explain these seemingly paradoxical associations, including inadequate control (both under and over) for potential confounders and/or factors in the causal pathway (e.g., nutritional status, cardiorespiratory fitness, hypertension), and/or more aggressive screening and treatment efforts in individuals classified as overweight or obese.^{5,11-13} In addition, the causes of death at low and high BMIs differ.^{5,14} Nevertheless, most research indicates that individuals at the highest end of the adiposity spectrum are at increased risk of mortality.^{5,13}

WHAT IS A DISEASE?

This seemingly straightforward question lacks a single, clear, authoritative, and widely-accepted definition.^{8,15-17} CSA Report 4-A-05 identified some common precepts in the definitions of disease provided by several dictionaries and encyclopedias (Table 2).¹ Similar attempts have varied in their conclusions about what constitutes a disease, particularly in relation to obesity.⁸ However, even the same definitions can yield varying conclusions. For example, the American Association of Clinical Endocrinologists (AACE) recently utilized the same disease criteria put forth in the previous CSA report and concluded that obesity does, in fact, meet those criteria.⁷ AACE's conclusion appears to be based less on new knowledge about obesity than on differences in their interpretation of the definition of disease.

In evaluating the variety of disease definitions currently in use (Table 2), some have noted that no one definition would encompass all diseases currently accepted as such (e.g., some definitions would exclude tuberculosis, stroke, alcoholism, some psychological disorders, or diabetes).⁸ Indeed, the medical community's definitions of disease have been heavily influenced by contexts of time, place, and culture as much as scientific understanding of disease processes.¹⁶ Given the often significant social and economic consequences of the dividing line between disease and "natural state" or "condition,"^{8,16} it is imperative to consider the potential advantages, disadvantages, incentives, and obligations of the disease label for patients, clinicians, employers, third party payers, policy makers, and society as a whole.⁸ Thus, rather than trying to determine if obesity meets arguably arbitrary disease criteria, the more relevant question is "would health outcomes be improved if obesity is considered a chronic, medical disease state?"⁸

WOULD CLASSIFYING OBESITY AS A DISEASE IMPROVE HEALTH OUTCOMES?

Various individuals and organizations have referred to obesity as a disease dating back to at least the 17th century, and possibly earlier--Hippocrates recognized the increased mortality risk of being overweight.⁸ However, members of both the general public and the medical community remain divided on this issue.^{8,15} While some arguments focus on whether obesity meets or does not meet the criteria for a specific definition of disease, other arguments directly address financial incentives for research and patient care, as well as the ability to offer treatment (Table 3). The financial and treatment arguments are particularly pertinent to the discussion of how classifying obesity as a disease might improve health outcomes; these arguments are considered in more detail below, along with arguments related to public policy, prevention programs, public perceptions and patient stigma.

Maybe Yes

More widespread recognition of obesity as a disease could result in greater investments by government and the private sector to develop and reimburse obesity treatments.^{7,8} Some argue that the Food and Drug Administration (FDA) would face increased pressure to approve medications for obesity, and would therefore reframe their approval process to focus on the ability of pharmaceuticals to decrease adipose tissue rather than to improve other markers of metabolic health, such as blood pressure and lipid levels.⁸ There is current interest in developing a “limited use” approval pathway that could facilitate the clinical review and FDA approval of prescription drugs. Antibiotics and drugs to treat obesity have been identified as appealing candidates for such a pathway. More effective medications on the market would likely spur physicians to prescribe, and patients to expect, pharmaceutical interventions for obesity.^{8,18} In turn, third party payers would be harder pressed to deny coverage.⁸

Public policy and prevention programs related to obesity may benefit from the greater urgency a disease label confers. More funding for obesity-prevention programs, particularly for children and adolescents, could lead to improved health outcomes for years to come.⁸ It is likely that a number of public policies related to healthy eating and physical activity, such as funding and regulations for K-12 meal programs and physical education, would receive greater attention and resources. Employers may be required to cover obesity treatments for their employees and may be less able to discriminate on the basis of body weight.⁸

Public perceptions may shift as a consequence of more extensive recognition of obesity as a disease, with greater appreciation of, and emphasis on, the complex etiology of obesity and the health benefits of achieving and maintaining a healthy weight.⁸ Lack of self-control, laziness, and other detrimental character attributes might be less likely to be associated with obese individuals, and in turn reduce stigmatization.^{8,19} The disease label also may provide greater motivation for some individuals to lose weight or maintain a healthy weight.⁸ While increased emphasis on obesity may increase stigma (see below), some have argued that such consequences would oblige the medical community to take greater action to protect patients’ rights.⁸

Maybe No

Concern exists that more widespread recognition of obesity as a disease would result in greater investments by government and the private sector to develop and reimburse pharmacological and surgical treatments for obesity, at the expense of clinical and public health interventions targeting healthy eating and regular physical activity.¹⁸ “Medicalizing” obesity could intensify patient and provider reliance on (presumably costly) pharmacological and surgical treatments to achieve a specific body weight, and lead to prioritizing body size as a greater determinant of health than health behaviors.^{18,20} Given the limitations of BMI (discussed above), this could also lead to the overtreatment of some people, such as those who meet the criteria for obesity, (i.e., BMI > 30) but are metabolically healthy. A similar concern is that obese individuals who improve their eating, physical activity, and sleeping habits, yet fail to lose enough weight to change their BMI classification, would still bear the “diseased” label and be pressured to receive medical treatment by clinicians, health insurers, and/or employers—even though their improved lifestyle behaviors are significant factors in preventing, delaying, and reducing the severity of obesity-associated outcomes. While some argue that BMI should be excluded from the definition of obesity in deciding whether or not obesity is a disease,^{7,8} the fact remains that BMI is currently the prevailing clinical measure of obesity.

It is possible that public policy and prevention programs related to obesity may be diminished if increased government financing of research into medical treatments reduces funds available for public health prevention programs.¹⁸ Similarly, the medicalization of obesity could detract from collective social solutions²⁰ to environmental forces that shape people’s behaviors and impact a number of conditions beyond just obesity.¹⁹ Thus, public efforts to enhance the built environment to make healthy eating and physical activity choices easier may receive less attention, despite providing substantial health benefits at every body weight;^{18,20} in turn, this could slow the improvement of health outcomes for all Americans. In addition, employers may raise health insurance premiums, limit hiring of obese individuals, and/or curtail employee wellness programs that incentivize weight loss or maintaining a healthy weight.⁸

Public perceptions may shift as a consequence of more extensive recognition of obesity as a disease, but not in a manner than improves health outcomes. For instance, some individuals may conclude that health behaviors matter little in disease development and management, which may decrease their motivation to eat healthfully and be physically active.⁸ In addition, an increased clinical emphasis on obesity could potentially offend or otherwise

alienate some obese individuals, particularly if the emphasis is on achieving an ideal weight rather than healthy eating and physical activity behaviors.¹⁹ Assuming the current BMI cut-points remain the primary clinical indicator of obesity, such stigma would likely also impact people who are otherwise healthy, but who nevertheless meet the criteria for obesity (BMI > 30)

AREAS REQUIRING FURTHER RESEARCH

If obesity is to be considered a disease, a better measure of obesity than BMI is needed to diagnose individuals in clinical practice. Further research is also warranted into the physiologic mechanisms behind why some obese individuals (e.g., the metabolically healthy obese) do not develop adverse health outcomes related to excess adipose tissue.²¹ This is particularly relevant given the difficulties most people have in achieving sustained weight loss. In addition, much more research is needed to develop effective and affordable obesity prevention and management strategies at both the clinical and community levels.

SUMMARY AND CONCLUSION

Without a single, clear, authoritative, and widely-accepted definition of disease, it is difficult to determine conclusively whether or not obesity is a medical disease state. Similarly, a sensitive and clinically practical diagnostic indicator of obesity remains elusive. Obesity, measured by BMI, is clearly associated with a number of adverse health outcomes, with greater consistency across populations at the highest BMI levels. However, given the existing limitations of BMI to diagnose obesity in clinical practice, it is unclear that recognizing obesity as a disease, as opposed to a “condition” or “disorder,” will result in improved health outcomes. The disease label is likely to improve health outcomes for some individuals, but may worsen outcomes for others.

What is clear is that a better measure of obesity than BMI alone is needed. NHLBI’s forthcoming guidelines on overweight and obesity in adults may help clarify clinical uncertainties regarding the best means of measuring obesity, at least in reference to cardiovascular risk. In the meantime, better clinical and public health strategies are warranted to assist individuals in improving their lifestyle behaviors and in reducing adverse outcomes associated with obesity.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted in lieu of Resolution 115-A-12 and the remainder of the report be filed.

1. That Policies H-150.953, “Obesity as a Major Public Health Program,” and H-440.866, “The Clinical Utility of Measuring Body Mass Index and Waist Circumference in the Diagnosis and Management of Adult Overweight and Obesity,” be reaffirmed.
2. That Policy H-150.953, “Obesity as a Major Public Health Program,” be re-titled “Obesity as a Major Public Health Problem.”
3. That Policy D-440.971, “Recommendations for Physician and Community Collaboration on the Management of Obesity,” be rescinded.

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TABLE 1. National Heart Lung and Blood Institute Classifications of Overweight and Obesity by BMI and Waist Circumference in Adults⁴

Classification	BMI (kg/m ²)	Risk of type 2 diabetes, hypertension, and CVD <i>relative to normal weight and waist circumference*</i>	
		Men ≤ 40 in; Women ≤ 35 in	Men ≥40 in; Women ≥ 35 in
Underweight	< 18.5	---	---
Normal weight	18.5 – 24.9	---	---
Overweight	25.0 – 29.9	Increased	High
Obesity (Class I)	30.0 – 34.9	High	Very High
Obesity (Class II)	35.0 – 39.9	Very High	Very High
Extreme obesity (Class III)	≥ 40	Extremely High	Extremely High

*NHLBI guidelines note that increased waist circumference can indicate increased disease risk even in individuals considered normal weight.

TABLE 2. Examples of disease definitions

Definition of disease
All 3 of the following criteria must be met: a) "An impairment of the normal functioning of some aspect of the body b) Characteristic signs or symptoms; and c) Resultant harm or morbidity to the entity affected" ¹
1) Based on biostatistical theory: "Deviation from species-typical functioning; disease is deviation from the average." -or- 2) Based on evolutionary functions: "Disease occurs when an organ is not performing the job that allowed it to evolve via natural selection." ⁸ (quoted in ⁸)
All 4 of the following criteria must be met: a) "A condition of the body, its parts, organs, or systems, or an alteration thereof; b) Resulting from infection, parasites, nutritional, dietary, environmental, genetic, or other causes; c) Having a characteristic, identifiable, marked, group of symptoms or signs; d) Deviation from normal structure or function (variously described as abnormal structure or function; incorrect function; <u>impairment of normal state; interruption, disturbance, cessation, disorder, derangement of bodily or organ functions</u>)." ²²
"Damage to an organ, part, structure, or system of the body such that it does not function properly (e.g., cardiovascular disease), or a state of health leading to such dysfunctioning (e.g., hypertension); except that diseases resulting from essential nutrient deficiencies (e.g., scurvy, pellagra) are not included in this definition." ²³
"An impairment of the normal state of the living animal or plant body or one of its parts that interrupts or modifies the performance of the vital functions, is typically manifested by distinguishing signs and symptoms, and is a response to environmental factors (as malnutrition, industrial hazards, or climate), to specific infective agents (as worms, bacteria, or viruses), to inherent defects of the organism (as genetic anomalies), or to combinations of these factors." ²⁴
1. "An interruption, cessation, or disorder of a body, system, or organ structure or function. 2. A morbid entity ordinarily characterized by two or more of the following criteria: recognized etiologic agent(s), identifiable group of signs and symptoms, or consistent anatomic alterations." ²⁵

TABLE 3. Arguments For and Against Classifying Obesity as a Medical Disease State*

Yes, Obesity is a Disease	No, Obesity is <i>Not</i> a Disease
Obesity meets disease criteria (e.g., outlined in CSA Report 4-A-05 ¹): a) <i>Impairment of normal functioning of the body</i> : "Appetite dysregulation, abnormal energy balance, endocrine dysfunction including elevated leptin levels and insulin resistance, infertility, dysregulated adipokine signaling, abnormal endothelial function and blood pressure elevation, nonalcoholic fatty liver disease, dyslipidemia, and systemic and adipose tissue inflammation." ⁷ b) <i>Characteristic signs and symptoms</i> : Increase in body fat has both anatomic sequelae (e.g., joint pain, immobility, sleep apnea) and metabolic sequelae (progression to type II diabetes and cardiovascular disease). ⁷ c) <i>Results in harm or morbidity to the entity affected</i> : Obesity is directly associated with increased mortality and morbidity due to a number of factors, and weight loss improves obesity-related morbidity and mortality (e.g., improved glycemic control in diabetes and reduced risk of type II diabetes, CVD, some cancers, and alleviation of symptoms of osteoarthritis, sleep apnea, etc.). ⁷	Obesity does NOT meet disease criteria (e.g., outlined in CSA Report 4-A-05 ¹): a) <i>Impairment of normal functioning of the body</i> : Excess adipose tissue is not necessarily an impairment; rather, it is a biological adaptation that can have beneficial effects. In fact, it is normal for the obese body to resist weight loss efforts. ¹ b) <i>Characteristic signs and symptoms</i> : There are no specific symptoms of obesity and the only sign is increased weight and body fat, which is the definition of obesity. ¹ c) <i>Results in harm or morbidity to the entity affected</i> : True causality has not been established in the literature, as obesity has only been associated with morbidity and mortality. ¹
Obesity is similar to other diseases (e.g., hypertension, diabetes, lung cancer) that result from a combination of genetics and environmental factors (including behaviors). ⁷	Simply because other diseases share similarities with obesity does not mean obesity is a disease. ⁸ Obesity results from personal choices to overeat or live a sedentary lifestyle, not an illness. ⁷

All diseases work through pathways and mechanisms; simply because obesity's anatomic and metabolic sequelae include already recognized diseases does not mean obesity is not also a disease. ⁸	Obesity is a modifiable risk factor - it increases risk of morbidity and/or mortality only by causing other diseases. ⁸
The disease label (i.e., "medicalization") would help improve attitudes and financial support to expand: a) research into prevention and treatment, and b) resources for patient care. ⁷	"Medicalization" of obesity is intended to drive financial gains of certain providers/interests. ⁸
Most experts agree obesity is a disease. ⁸	Just because most experts agree (if true) does not mean obesity meets the criteria for disease, and some experts disagree. ⁸
Obesity is treatable in at least some individuals but a lack of treatment should not be a criteria for considering obesity a disease. ⁸	There is no effective, well-established treatment for obesity. ⁸

*Arguments listed were discussed in the cited references, but do not necessarily reflect those authors' views.

APPENDIX – Current AMA policies relevant to the issue of obesity as a chronic medical disease state

H-150.953 Obesity as a Major Public Health Program

Our AMA will: (1) urge physicians as well as managed care organizations and other third party payers to recognize obesity as a complex disorder involving appetite regulation and energy metabolism that is associated with a variety of comorbid conditions; (2) work with appropriate federal agencies, medical specialty societies, and public health organizations to educate physicians about the prevention and management of overweight and obesity in children and adults, including education in basic principles and practices of physical activity and nutrition counseling; such training should be included in undergraduate and graduate medical education and through accredited continuing medical education programs; (3) urge federal support of research to determine: (a) the causes and mechanisms of overweight and obesity, including biological, social, and epidemiological influences on weight gain, weight loss, and weight maintenance; (b) the long-term safety and efficacy of voluntary weight maintenance and weight loss practices and therapies, including surgery; (c) effective interventions to prevent obesity in children and adults; and (d) the effectiveness of weight loss counseling by physicians; (4) encourage national efforts to educate the public about the health risks of being overweight and obese and provide information about how to achieve and maintain a preferred healthy weight; (5) urge physicians to assess their patients for overweight and obesity during routine medical examinations and discuss with at-risk patients the health consequences of further weight gain; if treatment is indicated, physicians should encourage and facilitate weight maintenance or reduction efforts in their patients or refer them to a physician with special interest and expertise in the clinical management of obesity; (6) urge all physicians and patients to maintain a desired weight and prevent inappropriate weight gain; (7) encourage physicians to become knowledgeable of community resources and referral services that can assist with the management of overweight and obese patients; and (8) urge the appropriate federal agencies to work with organized medicine and the health insurance industry to develop coding and payment mechanisms for the evaluation and management of obesity. (CSA Rep. 6, A-99; Reaffirmation A-09; Reaffirmed: CSAPH Rep. 1, A-09; Reaffirmation A-10; Reaffirmation I-10; Reaffirmation A-12; Reaffirmed in lieu of Res. 434, A-12)

H-440.902 Obesity as a Major Health Concern

The AMA: (1) recognizes obesity in children and adults as a major public health problem; (2) will study the medical, psychological and socioeconomic issues associated with obesity, including reimbursement for evaluation and management of obese patients; (3) will work with other professional medical organizations, and other public and private organizations to develop evidence-based recommendations regarding education, prevention, and treatment of obesity; (4) recognizes that racial and ethnic disparities exist in the prevalence of obesity and diet-related diseases such as coronary heart disease, cancer, stroke, and diabetes and recommends that physicians use culturally responsive care to improve the treatment and management of obesity and diet-related diseases in minority populations; and (5) supports the use of cultural and socioeconomic considerations in all nutritional and dietary research and guidelines in order to treat overweight and obese patients. (Res. 423, A-98; Reaffirmed and Appended: BOT Rep. 6, A-04; Reaffirmation A-10; Reaffirmed in lieu of Res. 434, A-12)

D-440.980 Recognizing and Taking Action in Response to the Obesity Crisis

Our AMA will: (1) collaborate with appropriate agencies and organizations to commission a multidisciplinary task force to review the public health impact of obesity and recommend measures to better recognize and treat obesity as a chronic disease; (2) actively pursue, in collaboration and coordination with programs and activities of appropriate agencies and organizations, the creation of a "National Obesity Awareness Month"; (3) strongly encourage through a media campaign the re-establishment of meaningful physical education programs in primary and secondary education as well as family-oriented education programs on obesity prevention; (4) promote the inclusion of education on obesity prevention and the medical complications of obesity in medical school and appropriate residency curricula; and (5) provide a progress report on the above efforts to the House of Delegates by the 2004 Annual Meeting. (Res. 405, A-03; Reaffirmation A-04; Reaffirmation A-07)

D-440.971 Recommendations for Physician and Community Collaboration on the Management of Obesity

Our AMA will: (1) work with the Centers for Disease Control and Prevention to convene relevant stakeholders to evaluate the issue of obesity as a disease, using a systematic, evidence-based approach; (2) continue to actively pursue measures to treat obesity as an urgent chronic condition, raise the public's awareness of the significance of obesity and its related disorders, and encourage health industries to make appropriate care available for the prevention and treatment of obese patients, as well as those who have co-morbid disorders; (3) encourage physicians to incorporate body mass index (BMI) and waist circumference as a component measurement in the routine adult physical examination, and BMI percentiles in children recognizing ethnic sensitivities and its relationship to stature, and the need to implement appropriate treatment or preventive measures; (4) promote use of our Roadmaps for Clinical Practice: Assessment and Management of Adult Obesity primer in physician education and the clinical management of adult obesity; (5) develop a school health advocacy agenda that includes funding for school health programs, physical education and physical activity with limits on declining participation, alternative policies for vending machines that promote healthier diets, and standards for healthy a la carte meal offerings. Our AMA will work with a broad partnership to implement this agenda; and (6) collaborate with the CDC, the Department of Education, and other appropriate agencies and organizations to consider the feasibility of convening school health education, nutrition, and exercise representatives, parents, teachers and education organizations, as well as other national experts to review existing frameworks for school health, identify basic tenets for promoting school nutrition and physical activity (using a coordinated school health model), and create recommendations for a certificate program to recognize schools that meet a minimum of the tenants. (CSA Rep. 4, A-05; Reaffirmation A-07; Reaffirmation I-07; Reaffirmed: CSAPH Rep. 1, A-08; Reaffirmation I-10; Reaffirmed: BOT Rep. 21, A-12)

H-425.994 Medical Evaluations of Healthy Persons

The AMA supports the following principles of healthful living and proper medical care: (1) The periodic evaluation of healthy individuals is important for the early detection of disease and for the recognition and correction of certain risk factors that may presage disease. (2) The optimal frequency of the periodic evaluation and the procedures to be performed vary with the patient's age, socioeconomic status, heredity, and other individual factors. Nevertheless, the evaluation of a healthy person by a physician can serve as a convenient reference point for preventive services and for counseling about healthful living and known risk factors. (3) These recommendations should be modified as appropriate in terms of each person's age, sex, occupation and other characteristics. All recommendations are subject to modification, depending upon factors such as the sensitivity and specificity of available tests and the prevalence of the diseases being sought in the particular population group from which the person comes. (4) The testing of individuals and of population groups should be pursued only when adequate treatment and follow-up can be arranged for the abnormal conditions and risk factors that are identified. (5) Physicians need to improve their skills in fostering patients' good health, and in dealing with long recognized problems such as hypertension, obesity, anxiety and depression, to which could be added the excessive use of alcohol, tobacco and drugs. (6) Continued investigation is required to determine the usefulness of test procedures that may be of value in detecting disease among asymptomatic populations. (CSA Rep. D, A-82; Reaffirmed: CLRPD Rep. A, I-92; Reaffirmed: CSA Rep. 8, A-03)

H-90.974 Opposition to Obesity as a Disability

Our AMA opposes the effort to make obesity a disability. (Res. 412, A-09)

H-440.866 The Clinical Utility of Measuring Body Mass Index and Waist Circumference in the Diagnosis and Management of Adult Overweight and Obesity

Our AMA supports: (1) greater emphasis in physician educational programs on the risk differences among ethnic and age groups at varying levels of BMI and the importance of monitoring waist circumference in individuals with BMIs below 35 kg/m²; (2) additional research on the efficacy of screening for overweight and obesity, using different indicators, in improving various clinical outcomes across populations, including morbidity, mortality, mental health, and prevention of further weight gain; and (3) more research on the efficacy of screening and interventions by physicians to promote healthy lifestyle behaviors, including healthy diets and regular physical activity, in all of their patients to improve health and minimize disease risks. (CSAPH Rep. 1, A-08)

D-440.952 Fighting the Obesity Epidemic

1. Our AMA Council on Science and Public Health (CSAPH) will critically evaluate the clinical utility of measuring body mass index (BMI) and/or waist circumference in the diagnosis and management of overweight and obesity, with input from leading researchers and key stakeholder organizations, with a report back at the 2007 AMA Interim Meeting. 2. Our AMA will consider convening relevant stakeholders to further examine the issue of incentives for healthy lifestyles. 3. Our AMA Council on Medical Service and CSAPH will collaborate to evaluate the relative merits of bariatric surgery and the issue of reimbursement for improving health outcomes in individuals with a BMI greater than 35. (BOT Rep. 9, A-07)

4. SAFETY OF X-RAY SECURITY SCANNERS (RESOLUTION 516-A-11 AND 518-A-11)

Reference committee hearing: see report of [Reference Committee E](#).

**HOUSE ACTION: RECOMMENDATIONS ADOPTED
IN LIEU OF RESOLUTIONS 516-A-11 AND 518-A-11 AND
REMAINDER OF REPORT FILED**
See Policy [H-455.994](#)

INTRODUCTION

Resolution 516-A-11 submitted by the Connecticut, Maine, Massachusetts, New Hampshire, Rhode Island and Vermont Delegations and referred by the House of Delegates asked:

That our American Medical Association (AMA) study the use of ionizing radiation in airport scanners and make appropriate recommendations to the federal government based on its findings.

Resolution 518-A-11 submitted by the New Mexico Delegation and referred by the House of Delegates asked:

That our AMA study the available information concerning the safety of whole body backscatter X-ray airport security scanners, with the intent of providing recommendations of a public health nature, including whether (1) additional studies should be undertaken; (2) there is sufficient evidence to suggest that specific regulations should be put into place to ensure that the scanners are performing according to clearly established specifications on an ongoing basis; (3) there is sufficient concern to recommend that some or all those who travel on commercial aircraft should decline to be scanned by X-ray scanners; and (4) there is sufficient concern to recommend that the Transportation Safety Administration consider the preferential use of alternative technology such as millimeter wave scanners in lieu of backscatter X-ray scanners.

The imperatives raised in these resolutions are diminished somewhat based on the US Transportation Security Administration's (TSA) decision early in 2013 to remove the backscatter models from US airports by June 2013 and replace them with millimeter wave models.¹ This followed an October 2012 announcement that the TSA had removed backscatter scanners from the majority of large airports, placing them in smaller airports.² According to news reports, the backscatter models removed from airports in 2013 will likely be placed in federal buildings and other locations in which security measures are needed.¹ Depending on the frequency of exposure for employees and visitors of locations in which the backscatter units may eventually be placed, the concerns raised in the resolutions continue to warrant examination.

BACKGROUND

Several years ago, the TSA began installing and using advanced imaging technology (AIT) at airport passenger screening checkpoints as a secondary measure to detect security threats. Early in 2010, AIT was widely implemented as a primary measure. AIT is more effective at detecting weapons, explosives, and other hazardous and/or concealed items hidden under clothing than older metal detector-based screening units. The two main types of AIT used are "backscatter" models, which use low levels of ionizing radiation, and "millimeter wave" models, which use radio waves. Comparative information about millimeter wave and backscatter screening models can be found in the Appendix.

Substantial debate on AIT has focused on privacy issues, since both backscatter and millimeter units are capable of producing extremely detailed images of passengers' bodies. That concern has been addressed by a Congressional mandate that detailed images of passengers' bodies be replaced with generic images of bodies, and in the case of backscatter screening, separating the screening personnel viewing the images from the passengers themselves. However, the TSA has stated that the company manufacturing the backscatter models could not meet a deadline to ensure that its software effectively produced generic images, and thus its contract was not renewed.¹

Debate also centers on exposure to ionizing radiation from backscatter screening. Although backscatter units use extremely low levels of ionizing radiation, concern exists that any increase in exposure to radiation is biologically

dangerous. Although few data exist about the safety of millimeter wave scanners, they are not believed to have carcinogenic potential. This report will therefore focus on the safety concerns associated with backscatter scanners.

METHODS

Literature searches were conducted in the PubMed database for English-language articles using the search terms “backscatter” and “x-ray” along with the terms “airport,” “security,” and “scanner.” Additionally, a Google search was conducted using the same search terms. Two comprehensive reports on the health effects of ionizing radiation,^{3,4} as well as several studies on radiation exposure from backscatter security scanners,⁵⁻⁹ also were consulted.

BIOLOGICAL EFFECTS OF EXPOSURE TO IONIZING RADIATION

Ionizing radiation refers to radiation that has sufficient energy to ionize atoms or molecules (cause separation of electrons from an atom) in biological systems. The electrons and positively-charged ions released as a result of ionization can cause cellular damage.³ X-rays, gamma rays, beta particles (high-speed electrons), neutrons (heavy uncharged particles), and alpha particles (heavy charged particles) are the principal types of ionizing radiation encountered. Of these types, x-rays and gamma rays have the lowest rate of energy transfer.⁴ Other types of radiation such as radio waves, visible light, and ultrasound do not produce ionization, and therefore have far less potential to cause biological damage.³

The free electrons generated by ionization of atoms in tissue are capable of causing DNA strand breaks and damaging nucleotide bases. Most damage to DNA can be repaired by the cell’s own mechanisms; however, if damage is not repaired correctly, the cell may become senescent (irreversibly dormant), undergo apoptosis that could lead to permanent tissue or organ damage, or retain a change in genetic sequence that sometimes leads to aberrant cell behavior such as uncontrolled cell division. The extent of damage to DNA, and thus the biological effects, depends on the type of ionizing radiation encountered, the dose delivered, and the time over which delivery occurs.³ For example, exposure to low-energy ionizing radiation such as x-rays produces far less biological damage than does exposure to the same dose of high-energy radiation such as alpha particles. In turn, cellular mechanisms can more effectively repair the damage caused by low-energy radiation.⁴

The average person is exposed to low levels of ionizing radiation during daily life from natural sources (background radiation) and other incidental or artificial sources, such as medical procedures and industrial or occupational exposure. The Table lists approximate exposure levels from common sources. The exposures are listed in Sieverts (Sv), a value that normalizes the biological effects of different types of ionizing radiation, leading to a calculation of equivalent dose that can be used to compare all types of ionizing radiation.¹ Total background radiation exposure, consisting of exposure to naturally-produced cosmic and terrestrial radiation, as well as inhaled and ingested radionuclides, is estimated to be 3.1 mSv per year for the average person.^{3,4} Another common source of ionizing radiation exposure is medical procedures, which vary widely in equivalent dose depending on the procedure.¹⁰ Air travel results in ionizing radiation exposure because of the increased exposure to cosmic rays at high altitudes; exposure during one minute at average flight altitude is estimated to be 0.04 μ Sv, with a transcontinental flight leading to an exposure of approximately 40 μ Sv.¹¹ Of note for the focus of this report, one backscatter scan has been reported to expose a person to 0.02-0.1 μ Sv.^{5-7,12} For the average person, the annual ionizing radiation exposure from all sources combined is approximately 6.2 mSv per yer.⁴

Cancer Risk from Low Level Ionizing Radiation

Estimating cancer risks from low-level radiation is difficult and imprecise. No studies have been comprehensive enough to quantify the risk; extremely large sample sizes (on the order of several million) are needed to accurately estimate risks from low-level exposure, making it unlikely that direct estimates of risk from very low doses will ever be possible.⁹ Instead, data from studies examining cancer risk from high-level radiation have been extrapolated to estimate the risk at low levels.¹³ However, extrapolation methods have been the subject of some disagreement. Some believe that linear extrapolation is appropriate, leading to the conclusion that even the most miniscule amounts of

¹ Sievert (Sv) is the SI unit of radiation dose equivalent. 1 Sv = 100 rem. Absorbed dose of radiation is expressed in rads. Since different types of radiation produce different amounts of damage per rad of dose, the Seivert takes into account the greater effects of certain types of radiation. A Seivert expresses the effectiveness of a particular kind of ionizing radiation relative to that of x-rays.

radiation proportionally increase the risk of cancer.^{4,14} Others argue that linear extrapolation is too simple and that thresholds exist under which cancer risk is nonexistent.^{11,14} Other factors contribute to the difficulty in estimating risk. Cancer risk from radiation exposure is heavily dependent on a person's age during exposure, with risk steadily decreasing as a person ages. Cancer risk also is dependent on whether exposure occurs acutely (such as that occurring from a nuclear accident or explosion of an atomic bomb) or over a protracted period (such as that occurring from occupational exposure).

In general, protracted exposure to low-energy ionizing radiation such as x-rays is associated with lower cancer risk than that resulting from acute exposure at the same total dose.⁹ The lowest acute dose thought to cause an increase in cancer risk is approximately 10-50 mSv.⁹ Exposure to approximately 50 mSv above background radiation over one year, or to 100 mSv above background radiation over a lifetime, also have been associated with an increased risk.⁹ For the general adult population, the excess lifetime risk for cancer is approximately 4.1-4.8% per Sv of exposure.^{9,15} Given that the average person is exposed to 6.2 mSv per year from background and other incidental sources,⁴ the excess risk of cancer from radiation exposure appears to be extremely low for most people.

Certain subsections of the population are especially sensitive to ionizing radiation. For example, neonates are roughly three times more sensitive to cancer-causing effects of radiation than is a 25 year-old adult.⁹ For developing embryos and fetuses exposed to ionizing radiation, the risk of congenital malformations is typically an order of magnitude higher than that of cancer risk.⁹ Some studies have suggested that 3-5% of the population is genetically hypersensitive to ionizing radiation, though no direct evidence exists identifying which subgroups have increased susceptibility to radiation-induced cancers, nor is it clear how significant the increase in risk may be for certain subgroups. Estimates for radiation-induced cancer risk for the general population are thought to be sufficiently stringent to protect the genetically sensitive subgroup.⁹

BACKSCATTER SECURITY SCANNERS

Backscatter scanning units direct an x-ray beam over the surface of the body; the x-rays are low intensity, and therefore do not travel deep into tissues or through the body as those of a medical x-ray would. Instead, the majority of the rays are reflected back from the skin. Detectors translate the reflection pattern into an image that is examined by security personnel. The backscatter pattern is dependent on material property, and thus distinguishes between organic and inorganic material.⁸

Radiation Exposure from Backscatter Scans

While most of the x-rays emitted during a backscatter scan are reflected back, a small number are absorbed by the body. Absorption is greatest in tissues located near the surface (skin, eyes, ribs, etc.), but lessens in deeper internal organs. Internal organs are estimated to absorb one-quarter of the radiation absorbed by the skin and other tissues near the surface of the body. Note that in the Table, the reported equivalent dose noted for one backscatter scan (0.02-0.1 μ Sv) pertains to the amount of radiation absorbed by the skin.

The amount of radiation exposure from one backscatter scan is exceedingly low. The National Council on Radiation Protection and Measurements (NCRP) considers a dose of 0.01 mSv or less per event to be negligible; exposure from a backscatter scan is approximately 100 times less than the negligible level.¹⁶ Exposure to the x-rays in one backscatter scan is equivalent to 3-9 minutes of background radiation exposure that occurs as part of daily living,¹⁷ and to 1-3 minutes of cosmic radiation exposure experienced during an airline flight. A person would have to undergo more than 50 backscatter scans to equal the amount of exposure from one dental x-ray, 4,000 scans to equal a mammogram, and 70,000 scans to equal one chest computed tomographic scan.¹⁸

Cancer Risks from Backscatter Scans

Note that many of the studies estimating cancer risks from backscatter scanners have assumed that millions of travelers would be exposed to them; as of June 2013 that will no longer be the case.

Extrapolated data point to a population risk of 0.08 cancers per Sv of exposure to ionizing radiation.¹⁷ Using that estimate, the cancer risk due to backscatter scanners has been estimated for all flyers and frequent flyers. For all flyers (100 million passengers representing 750 million enplanements per year), six additional cancers would occur over the lifetime of the group resulting from backscatter scans.¹⁷ However, it is important to note that 40 million

cancers will occur over the lifetime of the group due to underlying cancer incidence. Among one million frequent fliers, four additional cancers could occur due to backscatter scans.¹⁷ This should be compared to the 600 cancers that would occur from the exposure to radiation at flying altitudes, and the 400,000 cancers that would occur over the course of the group's lifetime due to underlying cancer incidence. The number of additional breast cancers that would occur in 5-year old female frequent fliers due to backscatter scans also has been estimated.¹⁷ For every two million women who travel one round trip per week, one additional breast cancer could occur over the lifetime of the group, compared to 250,000 breast cancers that will occur in this group over its lifetime due to the incidence of breast cancer.

Like the general public, segments of the population that are sensitive to radiation (pregnant women, children, and those who are genetically susceptible to cancer) appear to be in very little danger from backscatter scans. The NCRP dose limit of 1 mSv per year above background radiation was developed to include all segments of the population.^{18,19} Accordingly, children and pregnant women (and the embryos or fetuses that they are carrying) are adequately protected when the recommended public dose limit is applied. For comparison, a pregnant woman or child would need to undergo more than 10,000 backscatter scans (figuring an equivalent dose of 0.1 μ Sv per scan) in one year to reach the NCRP dose limit. Estimations of cancer risk from low-level ionizing radiation for those who are genetically susceptible to cancer (e.g., those who carry mutations in genes that increase cancer risk) remain unclear. Studies have demonstrated increased radiosensitivity for cells carrying certain mutations that increase cancer risk, but no studies have directly measured cancer risk from the levels of radiation used in backscatter scanners in genetically susceptible populations.⁴ As noted, the levels of radiation are so small that no study has been adequately powered to directly estimate cancer risks, and no extrapolated data exists suggesting that radiation doses from backscatter scanners are dangerous to those genetically predisposed to cancer.⁹

Oversight and Safety Evaluations of Backscatter Scanners

The Food and Drug Administration's (FDA) Center for Devices and Radiological Health (CDRH) is responsible for the oversight of radiation-producing equipment. Manufacturers of products that emit ionizing radiation (other than medical diagnostic equipment) must comply with the electronic product radiation control provisions of the Federal Food Drug and Cosmetic Act (FFDCA). Manufacturers of any electronic products that emit x-rays, including backscatter security systems, are required to submit a radiation safety report to FDA before entering products into commerce and file annual radiation safety reports.²⁰ In 1998, the FDA began addressing x-ray security scanners directly, working with the American National Standards Institute (ANSI) and the Health Physics Society to develop radiation safety standards for backscatter units. The standards, first published in 2002 and updated in 2009, state that facilities using backscatter units should ensure that no individual scanned receives a dose of more than 0.25 mSv per year, and that no individual should receive a dose of more than 0.25 μ Sv per scan.²¹ The standards also require that surveys be performed at regular intervals to measure emissions and ensure that ANSI limits are not being exceeded. The TSA requires that all AIT conform to the ANSI 2009 standards.

Additionally, under the provisions of the FFDCA, the manufacturer is required to investigate and report any accidental radiation occurrence and notify the FDA in the event that the manufacturer becomes aware of a defect. ANSI standards also require the manufacturer to establish and maintain records of any incidents involving unplanned exposures as reported by the user, and provide the information to the FDA.²¹ Backscatter scanners have operational interlocks that function to terminate x-ray production when inconsistencies, over-voltage, or over-current occurs.⁶

Since the deployment of backscatter scanners at airport security checkpoints, several entities have tested the units and concluded that they are safe for use. In January of 2012, the US Army Public Health Command conducted a study on the safety and operation of the Rapiscan 1000 (the most widely deployed backscatter model) at six airports across the country.⁵ It concluded that the Rapiscan 1000 system operates within the ANSI limit of 0.25 μ Sv per scan, and that an individual could be scanned up to 5,000 times per year without exceeding the ANSI annual dose limit of 0.25 mSv.⁵ In 2010, the Johns Hopkins University Applied Physics Laboratory was directed by the TSA to conduct a radiation safety assessment on the Rapiscan 1000 model, finding that individual doses were within ANSI limits, and below the NCRP negligible limit (0.01 mSv per event) as long as an individual underwent fewer than 684 screenings per year.⁶ In 2006, as part of an agreement between the TSA and the FDA, CDRH's Ionizing Radiation Measurements Laboratory evaluated x-ray emissions and dose to humans from the Rapiscan 1000 model, concluding that the system met ANSI standard requirements, with an average adult exposed to 0.024 μ Sv per scan.⁷ The Department of Homeland Security's Office of Inspector General (OIG) recently reviewed the TSA's standard

survey and maintenance practices for backscatter units, and found that the TSA was in compliance with ANSI survey requirements, radiation exposure levels were within ANSI limits, and no accidental radiation overdoses have occurred.⁸ In the report, the OIG recommended steps to be taken to improve the TSA's calibration practices, safety surveys following maintenance, and radiation safety training for screening personnel; the TSA agreed with the recommendations and is in the process of implementing them.⁸

In December of 2012, the Department of Homeland Security announced that it would award a contract to the National Academy of Sciences (NAS) to convene a committee to review previous studies and current processes used to estimate radiation exposure from backscatter units. The NAS will issue a report with recommendations on whether exposures comply with applicable health and safety standards, and whether the system design, operating procedures, and maintenance procedures are appropriate to prevent over-exposure to travelers.²² In addition, the American Association of Physicists in Medicine has convened a Task Group to study radiation emission from the Rapiscan 1000 unit, and plans to release a report in 2013.²³ The American College of Radiology has stated that it is not aware of any evidence that points to biological effects for passengers who are screened with backscatter units.²⁴

CONCLUSIONS

Despite concerns raised about ionizing radiation exposure from backscatter scanners, studies have concluded that exposure is exceedingly small, far less than the exposure considered negligible by the NCRP. No studies have demonstrated negative health effects in passengers scanned by backscatter units, and the cancer risk from exposure appears to be miniscule. The Council believes that no data currently exist to suggest that passengers should avoid being screened by backscatter scanners. However, it supports continued research on the safe use of the scanners, as well as maintenance, calibration, survey, and officer training procedures that are meant to ensure that the units operate as intended. The Council notes that passengers who do not wish to undergo backscatter screening may opt for alternative screening. The Council also notes that no adverse health consequences are known to occur from millimeter wave models that have replaced the backscatter models.²⁰

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statement be adopted in lieu of Resolutions 516-A-11 and 518-A-11, and that the remainder of the report be filed.

Our American Medical Association: (a) believes that as of June 2013, no data exist to suggest that individuals, including those who are especially sensitive to ionizing radiation, should avoid backscatter security scanners due to associated health risks; and (b) supports the adoption of routine inspection, maintenance, calibration, survey, and officer training procedures meant to ensure that backscatter security scanners operate as intended.

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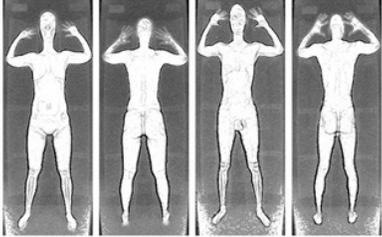
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Table. Common sources of radiation exposure

Radiation Source	*Equivalent dose ^{1-5,8-10}
Background (total)	3100 μ Sv/yr
Cosmic	270 μ Sv/yr
Terrestrial	190 μ Sv/yr
Inhaled (radon and other)	2290 mSv/yr
Internally deposited	310 μ Sv/yr
Ingesting one banana	0.1 μ Sv
Ingesting a 135 g bag of brazil nuts	5 μ Sv
Dental x-ray	5 μ Sv
Chest x-ray	20 μ Sv
Flight from New York City to Chicago	9 μ Sv
Transatlantic flight	70 μ Sv
Mammogram	400 μ Sv
Head CT scan	2000 μ Sv
Chest CT scan	7000 μ Sv
One minute at flight altitude	0.04 μ Sv
One backscatter security scan	0.02-0.1 μ Sv

* See footnote on page 1 for an explanation of the Sv unit.

APPENDIX. – Comparison of airport security scanners.²⁵

	Millimeter Wave	Backscatter
What does the unit look like?		
How does it work?	Radio frequency waves are beamed over the body using two rotating antennas. The energy reflected back from the body is converted to an image and analyzed.	A low-intensity x-ray beam is directed over the surface of the body. Rays that are reflected back to detectors are converted into an image and analyzed.
What type of energy is used?	Millimeter waves	Low levels of ionizing radiation
What do security personnel see?	The body image appears as a generic “Gumby-like” figure. 	The body image appears as a chalky outline. 
What is the risk determination process?	After the passenger stands in the phone-booth like scanner for a few seconds, a security officer inspects the image displayed on a monitor attached to the machine. If an irregularity is detected, a yellow box appears on the suspected part of the body and the passenger is inspected. If no irregularity is detected, a large “OK” sign is displayed.	After the passenger stands in the rectangular scanner for a few seconds, a security officer sitting in a different location looks at the image generated. If an irregularity is spotted, the officer attending to the passenger is notified and inspects the passenger. At the end of the process, the image is deleted.
Do safety standards exist?	Yes	Yes

5. HEALTH EFFECTS OF THE GULF OIL SPILL

Reference committee hearing: see report of [Reference Committee D](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS AND REMAINDER OF REPORT FILED

See Policy [D-135.980](#)

INTRODUCTION

At the 2010 Interim Meeting, the Council on Science and Public Health developed a brief report on contemporary views regarding health risks associated with the Gulf oil spill and summarized relevant activities of the American Medical Association.¹ Policy D-135.980, “Gulf Oil Spill Health Risks: Update on AMA Involvement,” directs the Council to report back at the 2013 Annual Meeting on the results of studies examining the health effects of the Gulf oil spill.

METHODS

English-language reports were selected from a PubMed search of the literature from April 2010 to March 2013 using the search terms, “gulf oil spill,” “deepwater horizon,” and “macondo,” alone and combined with “health,” or “health effects.” Additional studies and resources were identified from the reference list of materials reviewed. Additionally, relevant webpages of the US Environmental Protection Agency (EPA), Food and Drug Administration (FDA), Gulf of Mexico Research Initiative, and National Resource Damage Assessment (NRDA) were consulted for information.

BACKGROUND

The Deepwater Horizon disaster began on April 20, 2010 with a blowout of British Petroleum (BP) Exploration and Production Inc.’s Macondo well located ~1500 m deep and 84 km from Venice, Louisiana, continuing until the well was successfully capped 87 days later. This spill was unique in its magnitude, duration, location (deep sea floor) and how it was managed, including the use of subsurface dispersants and controlled surface burns.²

OIL SPILL DYNAMICS

Human and ecological effects of the oil spill are directly related to rate and the quantity of oil and gas/hydrocarbon mixture released and dispersants that were used. The oil flow rate was eventually estimated at ~50,000-70,000 barrels per day, modestly decreasing over the duration of the spill for a total of almost 5 million barrels (or > 200 million gallons).³ When an oil spill occurs underwater, plumes of oil droplets are formed that drift toward the ocean’s surface. Surface slicks undergo “weathering” through various processes including evaporation, emulsification, dispersion, dissolution, sinking/sedimentation, biodegradation (microbial), and photo-oxidation.

Approximately 25% of the oil was removed or recovered via direct recapture from the riser pipe, burning, or skimming, primarily in offshore waters north of the wellhead.⁴ Because of the characteristics of the Macondo oil (i.e., relatively light crude, enriched in low molecular weight compounds) and physical extremes of pressure and temperature at the well head, a substantial portion of the oil (23%) was physically dispersed/dissolved or evaporated on reaching the surface. Additionally, approximately 16% was chemically dispersed and 13% was degraded/consumed by bacteria. Little or no methane gas reached the ocean surface.⁵ The remainder of the oil (~23%) is unaccounted for. This category includes tar balls, and oil on beaches or in shallow subsurface mats and deep sea sediments.³

A significant portion of the oil that was dispersed (chemically and naturally) was consumed by bacteria that had evolved in deep Gulf waters where oil seeps are common.⁶ In the initial stages of May and June 2010, microbial community composition in the plume waters expanded and was highly enriched with previously uncharacterized oil-eating microbes capable of hydrocarbon and alkane degradation.⁷ Beds of microbial proliferation, oil consumption, bacterial secretions and subsequent death of microorganisms and/or plankton created dense accumulations (“marine snow”) comprising oily particulate matter and creating ocean floor sediment that may be several inches thick.⁸ By August 2010, oil had dissipated to background levels offshore, but grounded oil remained in both deepwater and

many shallow coastal areas around oiled marshes and near some beaches, potentially affecting some deep coral communities, shore birds, oysters, and sea turtles in particular.^{2,9,10}

Use of Dispersants

Dispersants are a mix of solvents, surfactants, and additives used to facilitate the breakup of oil into tiny droplets that are more easily broken down by natural processes. Approximately 1.8 million gallons of dispersant (primarily Corexit® 9500) were applied during the Deepwater Horizon incident. More than 40% of this volume was applied directly at the wellhead more than 5,000 feet below the ocean's surface, a technique that had not been used before. This use was intended to promote more rapid degradation of hydrocarbons, eventually doubling the amount of chemically-dispersed oil from approximately 8% to 16%. An unknown portion of the dispersant remained associated with the oil and gas phases of the underwater plume, apparently undergoing only negligible or slow rates of biodegradation.¹¹

The material data safety sheet for Corexit® 9500 identifies light petroleum distillates (10-30%), propylene glycol (1-5%) and organic sulfonic acid salt (10-30%) as hazardous substances.¹² The proprietary sulfonic acid derivative was later identified as dioctyl sodium sulfosuccinate, a commonly used stool softener for human use. Most water and sediment samples from near shore and offshore that were tested for major dispersant constituents did not exceed EPA's benchmark threshold for aquatic safety.^{13,14} Although the toxicity of crude oil alone was comparable to the toxicity of oil-dispersant mixtures in limited aquatic species testing,¹⁵ the long term implications and toxicity of dispersant-oil mixtures on myriad ocean species are largely unknown. Additional information is needed to better understand the risks of widespread dispersant use, especially subsurface application. See the Government Accountability Office report on oil dispersants for more discussion on the potential toxicity of oil dispersants and contemporary issues surrounding their use.¹⁶

SEAFOOD SAFETY

In recent years approximately 20% of the commercial seafood caught in US waters came from the Gulf of Mexico.¹⁷ During an oil spill, the National Oceanic and Aeronautic Administration (NOAA) has authority to close (and with the concurrence of the FDA, open) federal fishing waters (3-200 miles offshore), while states regulate fisheries in their coastal waters (0-3 miles offshore). Of greatest concern from the crude oil spill was exposure to higher molecular weight polycyclic aromatic hydrocarbons (PAH) and perhaps certain dispersant constituents. This concern was based on the capacity of these substances for environmental persistence, bioactivity and/or human toxicity. PAHs can potentially cause skin and lung cancer and are reproductive and developmental toxins. Susceptibility of marine life to potential harmful effects is influenced by differential rates of metabolism and disposition of PAHs. Finfish are least susceptible due to their high capacity to eliminate PAHs. Crustaceans are somewhat intermediate in their metabolic efficiency, while oysters have only a very limited ability to eliminate PAHs and thus are most susceptible to accumulation and toxicity.¹⁸

At its peak, more than one-third of federal waters were closed to fishing, as were most state waters extending from Louisiana to the panhandle of Florida. Reopening of federal waters required an oil free period of 30 days and repeated tests on different types of seafood sampled over multiple days based on a unified protocol involving sensory (smell) testing coupled with chemical analysis of 13 different PAHs and their alkylated homologs.¹⁹ The FDA estimated allowable thresholds (levels of concern or LOC) for PAHs intended to be protective of vulnerable populations. The risk assessment criteria differed for individual PAHs; some were based on a 5 year exposure for carcinogenic endpoints; others were based on a lifetime exposure estimate (noncarcinogenic endpoint). Sensory and chemical methods applied to >8,000 seafood specimens collected in federal waters of the Gulf found only low concentrations of PAHs, at least two orders of magnitude below levels of concern for human health based on the derived LOCs.²⁰ The assumptions used to create the FDA model have been criticized as not sufficiently protective of vulnerable populations (see Rotkin-Ellman et al).²¹ Ultimately, by April 2011 all federal fishing waters were reopened. It is generally believed that these measures prevented oil-contaminated seafood from reaching the market.²² Catastrophic losses of finfish populations in direct response to the oil spill itself were not observed.²³

HUMAN HEALTH EFFECTS

Human health effects can be divided into those caused by chemical exposures and mental health consequences. Exposed populations include more than 100,000 workers employed during the clean up phase and community

members with potential chemical exposures. Exposure routes include inhalation, dermal contact, ingestion of contaminated food or water, and contact with beach and soil residues.

Workers with Chemical Exposures

Worker exposure varied based on job assignment, training, and whether protective equipment was used effectively. Exposures were both offshore (booming and skimming; aerial and vessel dispersant release; in situ surface burning; containment and recovery work at the oil source) and onshore (beach and wildlife cleanup operations, decontamination and waste management activities). The National Institute of Occupational Safety and Health (NIOSH) catalogued a number of reported symptoms in workers including headaches, faintness, dizziness, or weakness, eye, nose, and throat irritation, lower respiratory symptoms, nausea and vomiting, and skin symptoms (itchy or red skin, or rash). Air sampling around off shore activities were unremarkable, and reported symptoms were considerably more prevalent in onshore work environments. For a summary of these findings see the final NIOSH health hazard evaluation summary report.²⁴ Exposure and health symptoms data²⁵ and additional analysis of injury and survey data also are available.²⁶

These findings apply only to acute exposures during the clean up phase. In order to examine potential long-term effects of exposure in clean-up workers and volunteers, the National Institute of Environmental Health Sciences (NIEHS) launched the GuLF STUDY (Gulf Long-term Follow-up Study) in February 2011. The study, which is enrolling up to 55,000 individuals, is expected to take 10 years and will be linked with various exposure scenarios based on area, job or task, date, geographic location and degree of exposure to weathered oil. The lapse in time between the start of the study and the activities of the response workers limits the use of comparative biologic markers of exposure and also may adversely affect recall accuracy.²⁷ Little evidence exists to support a significant effect of chemical exposure from the oil spill on the general health of community residents.²⁷

Mental Health

Previous oil spills and disasters have shown that affected populations experience mental health effects that can be widespread and significant.^{28,29} Evaluating mental health consequences of the Gulf oil spill is complicated by the fact that many areas were still recovering from Hurricane Katrina and coastal populations included those already suffering from a higher incidence of health disparities and poor health indices.²⁷

In the first several months after the spill, one-third of inhabitants of Gulf coast counties suffered loss of income coupled with rates of depression, anxiety, and negative quality of life indicators that exceeded baseline levels.³⁰ Such responses were significantly correlated with loss of income.³¹ A cross-sectional survey of more than 2500 Gulf coast residents revealed they were more likely than inland residents to score worse on the Emotional Health Index and to report a clinical diagnosis of depression.³² A follow-up survey two years later indicated that residents of Gulf coast-facing counties were 31% more likely to report having ever been diagnosed with depression in the first four months of 2012 than they were in the same time period before the oil spill, although some improvements were noted in general reports of stress, worry, and sadness.³³ Finally, nearly 20% of parents reported that a child in the family had experienced emotional or behavioral problems following the oil spill that were not previously existent.³⁴ Further information will be forthcoming from the Women and their Children's Health (WATCH) Study. WATCH is a prospective cohort study of the physical, mental and community health effects resulting from the spill and its aftermath among women and their children in seven coastal Louisiana parishes closest to the oil spill.

ECOLOGICAL EFFECTS

Wide-ranging areas of the Gulf of Mexico were contaminated with oil including deep sea communities and ~1600 kilometers of shoreline. Multiple species of marine life and birds were affected. In addition to EPA dispersant testing, several large scale field efforts were performed including subsea plume and post spill assessments, shoreline and wildlife oiling impact assessments, and assessments of near coastal areas and estuaries (see Barron for review).³⁵ Accordingly, hydrocarbon footprints in near shore coastal sediments and salt marshes have been characterized, and the direct effects of oil and dispersants on microbial and insect communities, vegetation, and various aquatic species have been examined (see Symposium for review).³⁶ Potential effects of the oil spill on food webs and lower trophic ecosystems of the open ocean also have received attention.³⁶ The relationship of myriad *in vitro* experiments indicating potential harmful effects to real world phenomena remain uncertain but reinforce the need for continued vigilance.

COMMENT

Environmental, aquatic and coastal habitats, human health, social, and economic impacts are still being documented and evaluated as part of the Natural Resource Damage Assessment (NRDA)³⁷ and the Gulf Long Term Follow-up Study of the NIEHS. The NRDA is overseen by trustees from the states of Texas, Louisiana, Mississippi, Alabama, and Florida, the Department of the Interior and the Department of Commerce. It will continue to assess damage to natural resources and the public's access and use of those resources for many years and will also design and implement restoration projects. Findings also will continue to emerge from the Gulf of Mexico Research Initiative, a nonprofit organization that is disbursing \$500 million donated by BP to scientists over 10 years. These peer-reviewed grants cover a wide range of topics including public health effects of the oil spill. The first interdisciplinary conference was held in January 2013.³⁶ Uncertainty remains about the potential for bioaccumulation of harmful residues. Accordingly, the overall impact of the Deepwater Horizon oil spill including human health effects, remains to be determined, but resources and mechanisms are in place to conduct long term assessments and remediation efforts.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted and the remainder of the report be filed.

1. That Policy D-135.980, "Gulf Oil Spill Health Risks: Update on AMA Involvement" be amended to read as follows.

Our AMA will encourage the National Institute of Environmental Health Sciences and the Natural Resource Damage Assessment program to: (1) continue to monitor health effects (including mental health effects) and public health surveillance activities related to the Gulf oil spill, and provide relevant information and resources as they become available; and (2) monitor report back at the 2013 Annual Meeting on the results of studies examining the health effects of the Gulf oil spill and report back as appropriate.

2. That Policy D-135.980 be renamed as follows:

Gulf Oil Spill Health Risks and Effects

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6. ELECTRONIC GAMES AND HEALTH PROMOTION

Reference committee hearing: see report of [Reference Committee D](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED AND REMAINDER OF REPORT FILED

Policy D-170.993 rescinded

INTRODUCTION

Policy D-170.993, “Electronic Games and Health Promotion,” directs our AMA to review and report on health-related use of electronic games, types of games that are available, and games that could be recommended by physicians for targeted patient populations.

BACKGROUND

The electronic gaming industry has been part of American culture since the late 1950s beginning with video games. It has grown exponentially in the last 20 years to include devices such as computers and smartphones. In 2011 alone, consumers spent \$24.75 billion on video games, hardware and accessories.¹ Today, the average US household owns at least one dedicated game console, PC, or smartphone.¹ While electronic games are often thought of as child’s play, the average game player today is 30 years old and has been playing games for 12 years.¹ Video games are often associated with males, however, 47% of all game players are women.¹ No longer a single player form of entertainment, 62% of gamers play games with others, either in-person or online.¹ These data lend credence to the notion that the health-related use of electronic games could potentially impact a wide range of individuals, including those who are difficult to reach with traditional messaging. Potential areas of influence include physical fitness, healthy habits, treatment, rehabilitation, as well as medical training for professionals.

Electronic games have often been the subject of controversy because of potential negative health implications associated with sedentary lifestyles or psychosocial effects. The Council previously studied the emotional and behavioral effects of video games and internet overuse.² While the effects and potential harms (including behavioral problems related to aggression) of video game usage in American youth have undergone increased public scrutiny, such games have a potentially positive role to play in the arenas of health care and health education. AMA Policy D-60.974, “Emotional and Behavioral Effects of Video Game and Internet Overuse,” encourages research on the positive effects of video games for people under age 18. See the Appendix for other AMA policies related to video games. This report focuses on research related to the positive use of electronic games for health improvement in the public and patient populations.

METHODS

English-language reports on studies involving human subjects were selected from a PubMed search of the literature from 2002 to February 2013 using the search terms, “video game,” “electronic game,” “game for health,” and “health game.” Additional studies and resources were identified from the reference list of materials reviewed.

TYPES AND USES OF ELECTRONIC GAMES FOR HEALTH BENEFITS

The use of electronic games for health improvement is an area of emerging research. Settings include homes, schools, hospitals, clinics, and community centers. Some games require physical interaction, whereas other games are non-active but are intended to be educational. Games also exist that combine efforts to increase knowledge with changes in attitudes and behaviors. Examples of innovative products include games for school-aged children to learn about nutrition, games for adults to aid in smoking cessation, games for seniors to demonstrate exercise, and games for college students which promote healthy lifestyles.³

Non-active games can increase knowledge and influence behavior change. For example, a game targeting adolescent cancer patients improved adherence to chemotherapy and treatment plans.⁴ Games that promote skill-building, virtual immersion in stories via avatars, goal setting, and situation simulation have shown promise in changing behavior; specific outcomes vary depending on game complexity.⁵ Video games also have shown success in

improving cognitive functions in healthy older adults, including task switching, working memory, visual short-term memory, and reasoning.^{6,7}

Active games also have shown promise for increasing an individual's physical activity. For example, one such game called Dance Dance Revolution (DDR) introduced in 1998 has sold nearly 16 million units worldwide.⁸ A 2005 study of DDR demonstrated that children dancing for 45 minutes doubled their resting heart rate and increased their metabolism and calories burned.⁹ The popular Nintendo Wii (2006) and Wii Fit (2008) gaming systems offer a variety of active games from boxing to tennis. Energy expenditure during active video games varies depending on weight, gender, intensity, and duration of activity.¹⁰ A recent study of Wii Fit games found that level of enjoyment influences frequency of game usage, thereby impacting energy expenditure. Aerobic games were found to produce greater energy expenditures than balance games ($\sim 2.7 \text{ kcal/kg}^{-1}/\text{hr}^{-1}$) although they were rated less enjoyable. Participation in aerobic games identified as more enjoyable produced greater energy expenditure than aerobic games designed to emphasize exercise alone.¹¹ One variable related to health promotion is that the nature of many active video games is often intermittent, thereby detracting from the gamer's ability to sustain movement and maintain aerobic exercise.¹⁰ For further information on the use of electronic media-based health interventions for promoting behavior change in youth (including physical activity and nutrition choices), see the recent systematic review by Hieftje et al.¹²

Other electronic games have the potential to enhance motor learning and training for cardio-vascular and musculoskeletal systems, and balance. For example, a study of patients in intensive care units indicated that active video game use is feasible and can complement routine physical therapy intended to improve balance and endurance.¹³ Another study of patients with spinal cord injury who used active video games requiring only upper limbs demonstrated increases in metabolic rates.¹⁴ Some believe that more investigation is needed to determine how to best include electronic games in clinical settings without disturbing the clinician-patient relationship, citing concerns regarding efficacy, suitability and safety.¹⁵

RESEARCH AND EVALUATION

As the field of electronic games for health continues to evolve, the challenge for designers, researchers, and health professionals is how to evaluate effectiveness. While games may impact short-term behavior among players, greater attention should be given to the design of games which promote long-term behavior change and are rooted in behavioral theories.^{16,9} The Robert Wood Johnson Foundation (RWJF) has invested in such research and evaluation. *Health Games Research (HGR): Advancing Effectiveness of Interactive Games for Health* is a national program founded in 2008 and headquartered at the University of California, Santa Barbara; funding is devoted to research that enhances the quality and impact of electronic games for health improvement.¹⁷ HGR encourages collaboration and creativity between design teams and researchers in order to develop new health games and game technologies that are engaging and enjoyable while at the same time can improve players' health-related behaviors and outcomes. HGR currently funds 21 research projects nationwide and hosts the annual Games for Health conference. Also, HGR created an online searchable database (<http://www.healthgamesresearch.org/db>) which provides information about hundreds of games, as well as related publications and resources. This database can be useful to health professionals and their staff who are interested in providing such information to their patients.

In May 2011, the National Heart, Lung, and Blood Institute, in collaboration with the Department of Defense Telemedicine and Technology Research Center, announced a grant program to foster healthy eating and physical activity, as well as self-care and other related behaviors. The goal of the program is to "develop the potential of virtual reality technologies as research tools for behavioral science-oriented studies in diabetes and obesity, and as practical tools for clinical and public health-level prevention and management of these conditions."¹⁸ The findings from this research may inform electronic game designers and health professionals alike.

Games for Health: Research, Development, and Clinical Applications is a new peer-reviewed journal that launched in 2012. The purpose of the journal is to create a forum for leaders in electronic gaming and those who research, recommend, design, publish, fund, and invest in electronic health games.^{19,20} While new, this journal intends to centralize emerging research and provide a consistent framework for evaluation.

CONCLUSIONS

A number of studies have been published in the last decade indicating that electronic games can be used for health improvement, including behavior change, particularly those that include goal-setting and the use of story.^{12,21} Active video games have the potential to improve otherwise sedentary behavior. Electronic games are indeed capable of providing light-to-moderate intensity physical activity, but they may not be able to significantly improve physical conditioning.²² Game designers are challenged to integrate more physical activity into enjoyable games, rather than just creating more exercise-themed games.¹¹ Substantial variability among studies of electronic games exists, including differences in game design, educational theories employed, and targets for change. This variability has made it difficult to equate game characteristics with outcomes. The potential for video games to promote improvements in health and safety behaviors, particularly in youth, calls for further research and more scientifically rigorous evaluation.¹²

Some of the appeal in using electronic games for health improvement is grounded in the fact they are relatively short in duration, replicable, commercially available, and relatively low cost. While much of the literature seems to focus on the impact of electronic games on children, more research on the adult population would be valuable, given that the average age of game players is 30 years.

For health care professionals, it would be helpful for game-makers to provide information on design principles and objectives in order to best determine suitability for patients. Wider promotion and dissemination of the results of the RWJF Health Games Research program could aid in that effort. (<http://www.healthgamesresearch.org/db>)

RECOMMENDATION

The Council on Science and Public Health recommends that Policy D-170.993 be rescinded and that the remainder of this report be filed.

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APPENDIX

D-170.993 Electronic Games and Health Promotion

Our AMA will review and report on health-related use of electronic games, types of games that are available, and games that could be recommended by physicians for targeted patient populations. (Res. 428, A-12)

D-60.974 Emotional and Behavioral Effects of Video Game and Internet Overuse

Our AMA: (1) urges agencies such as the Federal Trade Commission as well as national parent and public interest organizations such as the Entertainment Software Rating Board, and parent-teacher organizations to review the current ratings system for accuracy and appropriateness relative to content, and establish an improved ratings systems based on a combined effort from the entertainment industry and peer review; (2) will work with key stakeholder organizations such as the American Academy of Pediatrics and the American Academy of Family Physicians to (a) educate physicians on the public health risks of media exposure and how to assess media usage in their pediatric populations and (b) provide families with educational materials on the appropriate use of video games; (3) supports increased awareness of the need for parents to monitor and restrict use of video games and the Internet and encourage increased vigilance in monitoring the content of games purchased and played for children 17 years old and younger; (4) encourages organizations such as the Centers for Disease Control and Prevention, the National Science Foundation, and the National Institutes of Health to fund quality research (a) on the long-term beneficial and detrimental effects not only of video games, but use of the Internet by children under 18 years of age; and (b) for the determination of a scientifically-based guideline for total daily or weekly screen time, as appropriate; and (5) will forward Council on Science and Public Health Report 12-A-07, Emotional and Behavioral Effects of Video Game and Internet Overuse, to the American Psychiatric Association and other appropriate medical specialty societies for review and consideration in conjunction with the upcoming revision of the Diagnostic and Statistical Manual of Mental Disorders. (CSAPH Rep. 12, A-07)

D-515.991 Labeling of Video Game Content

Our AMA will actively campaign for appropriate labeling of any video game that depicts acts of violence or aggressive acts so that these videos will be made available for purchase by adults only. (Res. 421, A-05)

D-515.988 Warning Labels on Video Games

Our AMA Council on Science and Public Health will: (1) work in conjunction with all appropriate specialty societies to prepare a report reviewing and summarizing the research data on the emotional and behavioral effects, including addiction potential, of video games; and (2) develop recommendations for physicians, parents and legislators based on the findings of this report. (Res. 421, A-06)

7. GENETIC DISCRIMINATION AND THE GENETIC INFORMATION NONDISCRIMINATION ACT

Reference committee hearing: see report of [Reference Committee E](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED IN LIEU OF RESOLUTION 511 AND REMAINDER OF REPORT FILED

See Policy [H-65.969](#)

INTRODUCTION

Genetic discrimination and the fear of it have negative effects on the delivery of clinical care. The Genetic Information Nondiscrimination Act (GINA), passed nearly five years ago, is intended to protect individuals from genetic discrimination by health insurers and employers.¹ GINA was hailed as the “first major civil rights bill of the new century,”² and indeed, the fear of genetic discrimination appears to have lessened among some patients since its passage.³ However, GINA left unaddressed a number of areas in which individuals may experience genetic

discrimination; it does not extend to life, long-term care, or disability insurance, and certain populations are not protected by its provisions. Other federal and state laws provide a patchwork of varied protections.

Given the rapid advance of genomic technologies that are transforming health care, the Council believes that consistent, robust protections against genetic discrimination are needed and will help to foster patient trust and engagement in care that while considered cutting-edge, has already become standard for an increasing number of medical conditions and treatments. The Council has undertaken this review to briefly examine genetic discrimination and GINA and to identify gaps in protection and necessary steps toward strengthening protections.

METHODS

Literature searches were conducted in the PubMed database for English-language articles published between 2000 and 2013 using the search terms “genetic discrimination,” “genetic information nondiscrimination act” and “GINA,” for the purpose of identifying articles detailing the history and recent cases of genetic discrimination, the impact that fear of genetic discrimination has on clinical care, the protective provisions of GINA and other laws, and assertions for strengthening protections. To capture reports that may not have been indexed on PubMed, a Google search was also conducted using the same search terms. Additional articles were identified by manual review of the references cited in these publications. The Library of Congress, Government Printing Office, and state databases were consulted for legislative language.

THE GENETIC INFORMATION NONDISCRIMINATION ACT

In 2008, after 13 years of effort on the part of many advocacy organizations including the American Medical Association (AMA), Congress passed GINA nearly unanimously.¹ Then-President George W. Bush signed it into law on March 21, 2008. GINA addresses discrimination in two areas, health insurance and employment. A summary of GINA’s provisions can be found in the Table. Title I of GINA prohibits group and individual health insurers from using a person’s genetic information in determining eligibility or premiums and prohibits health insurers from requesting or requiring that a person undergo a genetic test in order to collect genetic information on that person for underwriting decisions.¹ Title II of GINA prohibits employers from using a person’s genetic information in making employment decisions such as hiring, firing, job assignments, or any other terms of employment; and prohibits employers from requesting, requiring, or purchasing genetic information about a person or their family members.¹

For the purposes of GINA, “genetic information” is defined as a person’s genetic test results, the genetic test results of a person’s family members (up to and including fourth-degree relatives), any manifestation of a disease or disorder in a family member, and participation of a person or family member in research that includes genetic testing, counseling, or education.¹ A “genetic test” refers to any test that assesses genotypes, mutations, or chromosomal changes;¹ for example, tests to detect hereditary breast or colorectal cancer mutations, examination of the genetic properties of a tumor, tests to diagnose a genetic disease such as Huntington’s, and carrier screening for disorders such as cystic fibrosis (CF).² Examples of tests that are not considered to yield genetic information are complete blood counts, cholesterol tests, and liver-function tests.²

Importantly, GINA does not prohibit health insurance underwriting or employment decisions based on current health status, including manifest disease of a genetic nature. Rather, it is intended to protect individuals with a genetic predisposition to disease that has not manifested, whether or not an individual has knowledge about that predisposition based on his or her own genetic test results or the genetic test results or manifestation of disease in a family member. GINA is based on the premise that it is unfair for a health insurer or an employer to make a decision about an individual based on a condition that may or may not actually develop in the future.⁴ Therefore, GINA is protective only before genetic conditions become manifest. Once a person is symptomatic, GINA is no longer protective.

GENETIC DISCRIMINATION

Genetic discrimination is considered the differential and adverse treatment of asymptomatic individuals based solely on their or their family members’ actual or presumed genetic characteristics.⁵

Cases of Genetic Discrimination

Well-documented instances of genetic discrimination have occurred in recent history. For example, in the 1970s, some states began to mandate sickle cell anemia screening for African-Americans. However, inadequate education and counseling about sickle cell disease resulted in confusion about the difference between carrying the sickle cell trait and having sickle cell disease.⁶ Healthy carriers of the sickle cell trait suffered adverse employment actions, and a stigma developed that African-Americans were inherently more susceptible to genetic disease than were members of other ethnic and/or racial groups.⁶

In 2001, the Equal Employment Opportunity Commission (EEOC) filed a claim against Burlington Northern Santa Fe for testing its employees who developed carpal tunnel syndrome for a rare genetic condition that is sometimes causal of the syndrome.⁷ Employees examined by company physicians were not told that the blood being drawn during the examination was being used for genetic testing. An employee who refused testing was threatened with termination.⁷

Several cases of health insurance discrimination have been published.⁸⁻¹² Below are examples.

- Two children who were carriers of a mutation that causes alpha-1 antitrypsin deficiency were denied coverage by their mother's health insurance company even though they would never develop the disease (alpha-1 antitrypsin deficiency is a recessive disease, so carriers who have only one copy of the mutation will not develop disease).
- A young boy who was a carrier of a mutation for Long QT Syndrome was denied coverage under his father's health insurance policy because of his "pre-existing condition," even though his condition was not manifest.
- A young woman who had undergone prophylactic mastectomy and hysterectomy was denied coverage when her health insurance company requested her medical records and discovered that she carried a *BRCA1* mutation associated with an increased risk of breast cancer.

Since the enactment of GINA's health insurance and employment provisions, only a modest number of genetic discrimination complaints have been filed under its provisions; in 2012, 280 cases of genetic discrimination were filed out of nearly 100,000 total discrimination cases filed.^{13,14} It is possible that the small number of cases reflects the effectiveness of GINA at discouraging the practice of genetic discrimination in the health insurance and employment sectors, or alternatively, discrimination continues to occur but is unrecognized or unreported, possibly because awareness of GINA is low.

Fear of Genetic Discrimination

Fears about genetic discrimination have led to refusal to undergo genetic testing among patients.¹⁵⁻¹⁸ This can result in serious health implications for individuals for whom genetic testing would be beneficial. Even among those who do undergo genetic testing, many withhold test results from their physicians, and some request that their results be placed in a "shadow chart" or withheld entirely from their medical record.¹⁸⁻²⁰ This lack of information can have detrimental effects on future care of the patient; treating physicians unfamiliar with the patient will have no record of genetic test results unless volunteered by the patient.

A majority of health care professionals surveyed also have expressed concern that their patients could experience discrimination after undergoing genetic testing.^{21,22} Survey data demonstrate that those with the strongest concern about genetic discrimination are more likely not to refer patients to genetics professionals (medical geneticists and genetic counselors), effectively preventing their patients from receiving optimal care.²³

Fear of genetic discrimination, on the part of both patients and physicians, also has detrimental effects on research. Potential research participants have refused to be part of genetic studies because of fear that their genetic test results might not remain confidential.¹⁶

Only a few studies assessing fear of genetic discrimination after the passage of GINA have been completed, but collectively, they find that despite the existence of GINA, fear has persisted among some groups. In a post-GINA survey of individuals who had considered genetic testing for hereditary breast and ovarian cancer, 60% indicated that they were worried about health insurance discrimination and 28% were worried about employment discrimination; 52%, 33%, and 34% were worried about life, disability, and long-term care insurance discrimination,

respectively.³ In another study, structured interviews with 64 patients at risk for genetic diseases revealed that they often did not trust how laws would work in real world circumstances, and would consider withholding genetic information or ask for it not to be included in their medical record.^{19,20}

Like patients, some health care providers continue to worry about genetic discrimination after the passage of GINA. In a survey of family physicians, 49%, 44%, and 42% were “highly concerned” about discrimination in life, health, and long-term care insurance, respectively.²⁴ More than 80% of obstetrician-gynecologists and oncologists also report that they are very or somewhat concerned about genetic discrimination.²⁵

Among patients reporting fear of genetic discrimination, improved knowledge of GINA and its protections appears to lessen the fear. After receiving information about GINA, more than half of individuals who had considered genetic testing for hereditary breast and ovarian cancer reported that the information made them less worried about genetic discrimination.³ However, unlike patients, knowledge of GINA does not appear to lessen the fear of genetic discrimination among physicians. In a survey, family physicians who were knowledgeable about GINA reported being no less concerned about genetic discrimination than were family physicians with little or no knowledge about it.²⁴ More research is required to examine this finding as it may be the result of several factors, including doubt about the real-world utility of GINA’s current protections or a belief that GINA’s current protections are inadequate.

PHYSICIAN ROLE IN PROTECTING AGAINST GENETIC DISCRIMINATION

Genomic-based technologies are becoming an increasingly routine part of medical care. Every newborn, with few exceptions, undergoes a panel of genetic tests (which is continually expanding) at birth to detect inherited conditions that are vitally important to treat early in life.²⁶ Several clinical guidelines now include genetic testing, and the safe and effective use of many drugs requires knowledge of the patient’s genotype.²⁷ Genetic tests are available for risk assessment, diagnosis, and/or management of nearly 3,000 diseases,²⁸ and whole-genome sequencing is gaining traction as a useful clinical tool.²⁹ Genomic data is also increasingly common in non-clinical applications. Direct-to-consumer genetic testing companies analyze customers’ DNA to reveal information about non-medical traits, and genealogy services analyze customers’ DNA samples to deliver information on genetic ethnicity.^{30,31} With more frequent use of technologies that involve analysis of patients’ genomic information, the potential for misuse and discrimination grows. In a troubling recent example, an 11-year old boy who carries a mutation for CF was reportedly ordered by school administrators to transfer to a different school for the protection of another student with CF, even though carriers do not pose a threat to those with CF or to anyone else.³²

Physicians have historically advocated for measures to safeguard against the inappropriate use of patients’ medical information, in part because use of such information to harm or penalize patients deters patients from seeking needed medical treatment. Fears of inappropriate use of medical information also undermine the truthful and accurate communication between patients and physicians essential to the provision of quality medical care.

Physician Knowledge of Protections Against Genetic Discrimination

A majority of physicians report being concerned about genetic privacy,³³ yet a gap in physician knowledge about GINA exists. For example, only approximately 10% of family physicians report being aware of GINA’s existence and have a basic understanding of its protections.²⁴

Although knowledge of GINA does not appear to reduce concerns about genetic discrimination among family physicians,²⁴ awareness of protections may have lessened the fear of genetic discrimination among other health care professionals. In a recent study, cancer genetics professionals who are familiar with protections afforded by federal laws other than GINA (the study was conducted before GINA’s passage) reported less concern about genetic discrimination than did non-genetics professionals who were unfamiliar with protections.³⁴ This may reflect the importance given to genetic information by cancer genetics professionals, but it also suggests that efforts toward educating all health care professionals about protections are warranted. Such education could lead to more appropriate referral for genetic services and increased uptake of genetic testing among patients, ultimately resulting in better patient care.³⁴ Education of consumers and patients is also important because fear of discrimination may prevent individuals from speaking to their physicians about genetic testing in the first place.³

Physicians have a duty to keep their patients’ genetic information confidential, yet dilemmas arise when such information has consequences for the patient’s family members. Many physicians feel obligated to inform and/or

treat relatives who may be at risk.²⁰ AMA Ethical Opinion E-2.131, “Disclosure of Familial Risk in Genetic Testing,” states that physicians in this situation should counsel patients on the implications of genetic information for their relatives, and identify circumstances under which they would expect patients to notify relatives about their own genetic test results. A basic understanding of the protections afforded by anti-discrimination laws is needed for physicians who will likely get questions about potential misuse of genetic information from patients and relatives.

ADEQUACY OF CURRENT PROTECTIONS

The persistent concern about genetic discrimination among some health care professionals and patients is not unreasonable given the shortcomings of GINA. While GINA prohibits discrimination by health insurers, it does not extend to life, long-term care, or disability insurance. Additionally, some groups are not afforded GINA’s protections. For example, employers with less than 15 employees are exempt from GINA’s employment discrimination provisions.³⁵ Also, patients obtaining care through the Veterans Health Administration (VHA) and the Indian Health Service also are not protected by GINA, nor are federal civilian employees participating in the Federal Employee Health Benefits Program or US military members participating in the Tricare program.³⁵ These exceptions exist because GINA amended existing health insurance and employment laws that do not apply to the aforementioned groups.³⁵ Some protections for these groups are afforded by Executive Orders (for federal civilian employees) or by internal policies similar to the protections afforded by GINA (US military and VHA).³⁵

In addition to GINA, other laws only partially protect against genetic discrimination in the health insurance realm. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 specifically lists genetic information as protected health information and explicitly states that a genetic risk factor for disease cannot be considered a preexisting condition.³⁶ HIPAA prevents health insurers from increasing the cost of an individual’s insurance discriminatorily, but insurance companies may raise an employer’s group premiums based on the genetic information of its employees as a whole.⁶ HIPAA also does not apply to the use of genetic information for individuals who purchase health insurance independently.⁶ The Affordable Care Act’s (ACA) protection against denial of health insurance due to preexisting conditions does not strengthen GINA’s protections, since genetic information is not considered a preexisting condition under the ACA.³⁷

In the employment realm, the Americans with Disabilities Act (ADA) prohibits employment discrimination based on a disability, the history of a disability, or a perceived disability.³⁸ However, it is not clear whether the ADA protects against genetic discrimination in employment decisions.³⁹ EEOC guidelines appear to conflict with court decisions that suggest genetic test results may be used in employment decisions.⁶

Adding complexity to the shortcomings of GINA is the patchwork of state laws addressing genetic discrimination. Slightly fewer than half of US states have laws providing additional protection against discrimination in aspects of life, long-term care, and disability insurance, as well as in other areas, that are not present in GINA.^{6,40} For example, California law prohibits genetic discrimination in such areas as housing, mortgage lending, education, life insurance and elections.⁴¹ Arizona statute prohibits the use of genetic information in the underwriting of life and disability insurance policies.⁴² In contrast, many states’ protections are no more strict than those afforded by GINA.⁴⁰ Importantly, in states that provide more comprehensive protections than those provided by GINA, GINA does not preempt state law.

The shortcomings of GINA and other federal laws along with the inconsistency in state laws leave many patients vulnerable to genetic discrimination and misuse of their genetic information. Further, physicians are placed in the difficult position of explaining to patients confusing genetic discrimination protections that vary by state and by individual circumstance.

A very important additional consideration is how difficult it has become to maintain the privacy and security of genomic information. In October 2012, the Presidential Commission for the Study of Bioethical Issues concluded that efforts to de-identify such information are exceptionally challenging and will gradually become impossible.⁴³ Indeed, in January 2013, a group of scientists demonstrated that the genetic information provided by individuals who had been assured anonymity can in fact be re-identified.⁴⁴⁻⁴⁶ Therefore, given the rapid uptake of genomic-based technologies in both the clinical setting and outside the clinic, there is a pressing need to move quickly to mitigate inappropriate uses of genomic information. It is often asserted that the important protections that GINA currently provides should be extended to cover other areas in which individuals could experience genetic discrimination, such as in life, long-term care, and disability insurance coverage.^{6,43,47}

AMA POLICY ON GENETIC DISCRIMINATION

AMA policy and Ethical Opinion relating to genetic discrimination is listed in Appendix 1. Briefly, AMA policy explicitly supports prohibitions on the use of genetic information in the context of health insurance. Policy H-185.972, “Genetic Information and Insurance Coverage,” states that health insurance providers should be prohibited from: 1) using genetic information to deny or limit any health benefit coverage; 2) establishing differential rates or premium payments; 3) requesting or requiring collection or disclosure of genetic information; and 4) releasing genetic information without express prior written authorization of the individual. Policy H-165.856, “Health Insurance Market Regulation,” similarly states that an individual’s genetic information should not be used to determine his or her health insurance premium. Ethical opinions further address genetic information as it relates to genetic discrimination in health insurance. E-2.135, “Insurance Companies and Genetic Information,” and E-2.137 “Ethical Issues in Carrier Screening of Genetic Disorders,” state that genetic testing results should not be shared with health insurers or other third parties, and that health care providers should ensure that genetic testing results are removed before fulfilling requests to share medical records.

In the employment context, AMA policy is silent. However, Ethical Opinion E-2.132, “Genetic Testing by Employers,” states that it is generally inappropriate to exclude workers with genetic risks of disease from the workplace because of their risk, and that the use of genetic testing to make employment decisions can result in unfair discrimination.

Lengthy AMA policy generally addresses patient privacy and confidentiality (H-315.983, “Patient Privacy and Confidentiality”), stating that genetic information should be kept confidential and should not be disclosed to third parties without the explicit informed consent of the tested individual. It further directs the AMA Board of Trustees to monitor and support federal legislation that will afford patients protection against discrimination on the basis of genetic testing.

AMA Legislative Principles

Early in 2013, the AMA Council on Legislation studied the issue of genetic discrimination and developed a set of legislative principles that could guide AMA advocacy activities in the absence of explicit AMA policy. The complete text of the principles can be found in Appendix 2. Briefly, the principles state that prohibitions on genetic discrimination are essential to advancements in medical knowledge and clinical care, and it is part of a physician’s duty to safeguard against the inappropriate use of patient medical information for non-medical purposes and to promote open and honest patient-physician communications. The principles further state that comprehensive federal protections against genetic discrimination are needed since patients remain at risk of discrimination in a broad array of areas. The AMA Board of Trustees approved the principles in March of 2013.

CONCLUSIONS

The AMA has been a strong opponent of discrimination based on genetic information, in part because patient care is negatively impacted by fear of such discrimination. GINA has afforded important protections, and increased awareness of it may reduce the fear. However, GINA leaves individuals vulnerable to discrimination in areas such as life, long-term care, and disability insurance, and does not extend to certain sectors of the population. Physicians are impeded in the delivery of care when patients are not forthcoming about genetic information or ask for measures such as withholding genetic information from medical records. Physicians also may be expected to be unreasonably fluent in detailed legal nuances of current protections. The Council believes that the increasingly common uses of genetic information both inside and outside of the clinical setting and the difficulty in maintaining the privacy of individuals’ genetic information, combined with the negative impact of the fear of genetic discrimination on patient care, make it essential that robust and comprehensive protections against genetic discrimination and misuse of genetic information be enacted. Such protections would benefit physicians, the research community, and most importantly, patients.

RECOMMENDATIONS

The Council on Science and Public Health recommends that the following statements be adopted and the remainder of this report be filed:

1. That our American Medical Association (AMA) strongly oppose discrimination based on an individual's genetic information.
2. That our AMA pursue and support legislation intended to provide robust and comprehensive protections against genetic discrimination and misuse of genetic information.
3. That our AMA support education for health care providers and patients on the protections against genetic discrimination currently afforded by federal and state laws.

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Table. Details of the Genetic Information Nondiscrimination Act (GINA). Adapted from Hudson et al., 2008.²

What GINA does
Prohibits group and individual health insurers from using a person's genetic information in determining eligibility or premiums
Prohibits an insurer from requesting or requiring that a person undergo a genetic test
Prohibits employers from using a person's genetic information in making employment decisions such as hiring, firing, job assignments, or any other terms of employment
Prohibits employers from requesting, requiring, or purchasing genetic information about persons or their family members
Enforced by the Department of Health and Human Services, the Department of Labor, and the Department of Treasury, along with the Equal Opportunity Employment Commission; remedies for violations include corrective action and monetary penalties
What GINA does not do
Does not prevent health care providers from recommending genetic tests to their patients
Does not mandate coverage for any particular test or treatment
Does not prohibit medical underwriting based on current health status, including manifest disease of a genetic nature
Does not cover life, disability, or long-term-care insurance
Does not apply to members of the military or federal civilian employees
Key terms
"Genetic information" includes information about:
A person's genetic tests
Genetic tests of a person's family members (up to and including fourth-degree relatives)
Any manifestation of a disease or disorder in a family member
Participation of a person or family member in research that includes genetic testing, counseling, or education
"Genetic tests" refers to tests that assess genotypes, mutations, or chromosomal changes
Examples of tests that would yield protected genetic information are:
Tests for BRCA1/BRCA2 (breast cancer) or HNPCC (colon cancer) mutations
Classifications of genetic properties of an existing tumor to help determine therapy
Tests for Huntington's disease mutations
Carrier screening for disorders such as cystic fibrosis, sickle cell anemia, spinal muscular atrophy, and fragile X syndrome
Examples of tests that would <u>not</u> yield protected genetic information are:
Routine tests such as complete blood counts, cholesterol tests, and liver-function tests

APPENDIX 1 – AMA Policy and Ethics Opinions Relating to Genetic Discrimination

H-185.972 Genetic Information and Insurance Coverage

AMA believes: (1) Health insurance providers should be prohibited from using genetic information, or an individual's request for genetic services, to deny or limit any health benefit coverage or establish eligibility, continuation, enrollment or contribution requirements. (2) Health insurance providers should be prohibited from establishing differential rates or premium payments based on genetic information or an individual's request for genetic services. (3) Health insurance providers should be prohibited from requesting or requiring collection or disclosure of genetic information. (4) Health insurance providers and other holders of genetic information should be prohibited from releasing genetic information without express prior written authorization of the individual. Written authorization should be required for each disclosure and include to whom the disclosure would be made. (BOT Rep. 15, I-96; Reaffirmed: CMS Rep. 8, A-06; Reaffirmed in lieu of Res. 102, A-10)

H-315.983 Patient Privacy and Confidentiality

(1) Our AMA affirms the following key principles that should be consistently implemented to evaluate any proposal regarding patient privacy and the confidentiality of medical information: (7) Genetic information should be kept confidential and should not be disclosed to third parties without the explicit informed consent of the tested individual. (17) Our AMA Board of Trustees will actively monitor and support legislation at the federal level that will afford patients protection against discrimination on the basis of genetic testing. (BOT Rep. 9, A-98; Reaffirmation I-98; Appended: Res. 4, and Reaffirmed: BOT Rep. 36, A-99; Appended: BOT Rep. 16 and Reaffirmed: CSA Rep. 13, I-99; Reaffirmation A-00; Reaffirmed: Res. 246 and 504 and Appended Res. 504 and 509, A-01; Reaffirmed: BOT Rep. 19, I-01; Appended: Res. 524, A-02; Reaffirmed: Sub. Res. 206, A-04; Reaffirmed: BOT Rep. 24, I-04; Reaffirmed: BOT Rep. 19, I-06; Reaffirmation A-07; Reaffirmed: BOT Rep. 19, A-07; Reaffirmed: CEJA Rep. 6, A-11; Reaffirmed in lieu of Res. 705, A-12)

H-165.856 Health Insurance Market Regulation

Our AMA supports the following principles for health insurance market regulation: (4) Strict community rating should be replaced with modified community rating, risk bands, or risk corridors. Although some degree of age rating is acceptable, an individual's genetic information should not be used to determine his or her premium; (CMS Rep. 7, A-03; Reaffirmed: CMS Rep. 6, A-05; Reaffirmation A-07; Reaffirmed: CMS Rep. 2, I-07; Reaffirmed: BOT Rep. 7, A-09; Res. 129, A-09; Reaffirmed: CMS Rep. 9, A-11; Reaffirmed in lieu of Res. 811, I-11; Reaffirmed in lieu of Res. 109, A-12; Reaffirmed in lieu of Res. 125, A-12; Reaffirmed: Res. 239, A-12)

E-2.132 Genetic Testing by Employers

As a result of the human genome project, physicians will be able to identify a greater number of genetic risks of disease. Among the potential uses of the tests that detect these risks will be screening of potential workers by employers. Employers may want to exclude workers with certain genetic risks from the workplace because these workers may become disabled prematurely, impose higher health care costs, or pose a risk to public safety. In addition, exposure to certain substances in the workplace may increase the likelihood that a disease will develop in the worker with a genetic risk for the disease. (1) It would generally be inappropriate to exclude workers with genetic risks of disease from the workplace because of their risk. Genetic tests alone do not have sufficient predictive value to be relied upon as a basis for excluding workers. Consequently, use of the tests would result in unfair discrimination against individuals who have positive test results. In addition, there are other ways for employers to serve their legitimate interests. Tests of a worker's actual capacity to meet the demands of the job can be used to ensure future employability and protect the public's safety. Routine monitoring of a worker's exposure can be used to protect workers who have a genetic susceptibility to injury from a substance in the workplace. In addition, employees should be advised of the risks of injury to which they are being exposed. (2) There may be a role for genetic testing in the exclusion from the workplace of workers who have a genetic susceptibility to injury. At a minimum, several conditions would have to be met: (a) The disease develops so rapidly that serious and irreversible injury would occur before monitoring of either the worker's exposure to the toxic substance or the worker's health status could be effective in preventing the harm. (b) The genetic testing is highly accurate, with sufficient sensitivity and specificity to minimize the risk of false negative and false positive test results. (c) Empirical data demonstrate that the genetic abnormality results in an unusually elevated susceptibility to occupational injury. (d) It would require undue cost to protect susceptible employees by lowering the level of the toxic substance in the workplace. The costs of lowering the level of the substance must be extraordinary relative to the employer's other costs of making the product for which the toxic substance is used. Since genetic testing with exclusion of susceptible employees is the alternative to cleaning up the workplace, the cost of lowering the level of the substance must also be extraordinary relative to the costs of using genetic testing. (e) Testing must not be performed without the informed consent of the employee or applicant for employment. (IV) Issued June 1991 based on the report "Genetic Testing by Employers," adopted June 1991 (JAMA 1991; 266: 1827-1830).

E-2.135 Insurance Companies and Genetic Information

Physicians should not participate in genetic testing by health insurance companies to predict a person's predisposition for disease. As a corollary, it may be necessary for physicians to maintain separate files for genetic testing results to ensure that the results are not sent to health insurance companies when requests for copies of patient medical records are fulfilled. Physicians who withhold testing results should inform insurance companies that, when medical records are sent, genetic testing results are not included. This disclosure should occur with all patients, not just those who have undergone genetic testing. (IV) Issued June 1994 based on the report "Physician Participation in Genetic Testing by Health Insurance Companies," adopted June 1993; Updated June 1996.

E-2.137 Ethical Issues in Carrier Screening of Genetic Disorders

All carrier testing must be voluntary, and informed consent from screened individuals is required. Confidentiality of results is to be maintained. Results of testing should not be disclosed to third parties without the explicit informed consent of the screened individual. Patients should be informed as to potential uses for the genetic information by third parties, and whether other ways of obtaining the information are available when appropriate. Carrier testing should be available uniformly among the at-risk population being screened. One legitimate exception to this principle is the limitation of carrier testing to individuals of childbearing age. In pursuit of uniform access, physicians should not limit testing only to patients specifically requesting testing. If testing is offered to some patients, it should be offered to all patients within the same risk category. The direction of future genetic screening tests should be determined by well-thought-out and well-coordinated social policy. Third parties, including insurance companies or employers, should not be permitted to discriminate against carriers of genetic disorders through policies which have the ultimate effect of influencing decisions about testing and reproduction. (IV, V) Issued June 1994 based on the report "Ethical Issues in Carrier Screening for Cystic Fibrosis and Other Genetic Disorders," adopted June 1991.

APPENDIX 2 – AMA Legislative Principles on Genetic Discrimination and Surreptitious Testing (Approved by the Board of Trustees in March 2013)

1. Physicians support efforts to prohibit genetic discrimination broadly as well as surreptitious testing, because they are essential to advancements in medical knowledge and clinical care, and because part of a physician's duty is to safeguard against the inappropriate use of patient medical information for non-medical purposes and promote open and honest physician-patient communications.
2. Comprehensive federal protection against genetic discrimination is needed because patients remain at-risk of discrimination in a broad array of areas such as life, long-term care, and disability insurance as well as housing, education, public accommodations, mortgage lending, and elections.
3. Federal law should not preempt state laws that provide a greater level of protection against genetic discrimination.

8. NATIONAL DRUG SHORTAGES: UPDATE

Reference committee hearing: see report of [Reference Committee E](#).

**HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS
IN LIEU OF RESOLUTIONS 508, 510 AND 517 AND
REMAINDER OF REPORT FILED
PROPOSED AMENDMENT REFERRED**

See Policy [H-100.956](#)

INTRODUCTION

Policy H-100.956, “National Drug Shortages,” directs the Council on Science and Public Health to continue to evaluate the drug shortage issue and report back at the 2013 Annual Meeting of the House of Delegates on progress made in addressing drug shortages. This report accomplishes that task.

METHODS

English-language reports were selected from a PubMed and Google Scholar search from 2011 to April 15, 2013, using the MeSH terms “pharmaceutical preparations,” or “generics/economics,” in combination with “supply/distribution,” and using the text term “drug shortages.” Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the US Food and Drug Administration (FDA), American Society of Health-System Pharmacists (ASHP), the Generic Pharmaceutical Association (GPhA), and from recent presentations on the topic at special organizational meetings at which the AMA was represented.

CURRENT DRUG SHORTAGES

Data on drug shortages come from various points across the supply chain.¹ Title X of the Food and Drug Administration Safety and Innovation Act of 2012 (P.L. 112-144; FDASIA) includes an “early notification clause” that instructs manufacturers of drugs that are “life-supporting, life-sustaining, and intended for use in the prevention or treatment of a debilitating disease or condition, including those used in emergency medical care or surgery” to notify the Food and Drug Administration (FDA) 6 months in advance (or as soon as possible) if manufacturing is going to be interrupted or discontinued.² Accordingly, the industry supplies voluntary information on inventory/production data and supply interruptions. If the product is a controlled substance, the FDA notifies the Drug Enforcement Administration in an effort to adjust nationwide production quotas if necessary. Failure to notify is not subject to an enforcement penalty, but companies that do not comply will be publicly identified in an annual report. At this point, the voluntary notification approach is working according to FDA staff.

Wholesalers also may voluntarily submit information on inventory/supply interruptions. Additionally, information on drug shortages is derived from hospital reports or less commonly from individual practitioners or the public. Sometimes, sales and market share data indicating a developing shortage are available to FDA from IMS Health.

Other features of Title X include: (1) enabling FDA to expedite review of a new or abbreviated drug application to mitigate a potential drug shortage; (2) requiring FDA to form a dedicated task force (see below); (3) requiring FDA to maintain a drug shortages list; (4) permitting hospitals to repackage medication in short supply (except controlled substances) into smaller volume doses for use within a specific health system, defined as a collection of hospitals that are owned and operated by the same entity and share access to databases with drug order information. Title X also requires the Government Accountability Office to conduct an extensive review of the myriad underlying causes of drug shortages and to recommend solutions to alleviate drug shortages; AMA staff provided input to the GAO for this report. Finally, the FDA also must provide an annual report to Congress that includes, among other things, a list of actions taken by the agency to mitigate drug shortages, and the number and description of the instances where FDA has used regulatory flexibility to prevent or alleviate shortages.

Trends in Shortages

As previously discussed, the FDA tracks and focuses on shortages of “medically necessary” drugs.³ A medically necessary drug product is one that is “used to treat or prevent a serious disease or medical condition for which there is no other alternative drug, available in adequate supply, that is judged by medical staff to be an adequate substitute.” The drug shortage resource center maintained by the American Society of Health-System Pharmacists (ASHP) tracks a somewhat broader array of drug and biological product shortages based largely on reports from hospital pharmacists. In some cases these are local or regional shortages.

The FDA successfully prevented 282 shortages in 2012, a substantial increase from the 195 shortages FDA prevented in 2011.^{4,5} One hundred seventeen new shortages of medically necessary drugs occurred in 2012, significantly fewer than the 251 shortages that were recorded in 2011.⁵ FDA believes that the early notification requirement of FDASIA is one important contributing factor in this trend. As of April 19, 2013, the FDA identified a total of 125 shortages of medically necessary products, a number that is comparable to the situation in August 2012.⁴ In contrast, the ASHP drug shortages resource center identified more than 230 drug shortages as of April 19, 2013, a number that is about 5% higher than the number of shortages catalogued by ASHP in August 2012.⁶ New shortages appear to be decreasing, but it is taking longer to resolve existing shortages.

Reasons for Drug Shortages

Solutions to the drug shortage crisis require understanding the causes. Approximately one-third of the shortages in 2012 were triggered by findings emanating from an FDA inspection, while more than one-half were related to self-reported findings or causes.⁵ In 2012, shortages of medically necessary drugs were evenly divided between “quality” and “delays/capacity” issues together accounting for 54% of such shortages. Product discontinuations (13%) and problems with the raw materials for active pharmaceutical ingredients (9%) accounted for 22% of shortages. In some cases, shortages resulted from manufacturing failures for one drug that increased demand for another drug and companies producing the latter were unable to meet demand (3%). The causes of 20% of drug shortages in 2012 were not identified or reported.⁵

Sterile Injectables

Sterile injectables continued to comprise the vast majority of shortages (72%) in 2012.⁵ Intravenous nutrition products, electrolytes, emergency medicines, anesthesia, and cancer drugs have been most affected recently. Shortages of sterile injectables are directly linked with the state of the industry as just five manufacturers supply the majority of the market for these products.¹

Most facilities producing generic sterile injectables are based in the United States because of high transportation costs associated with liquids that require climate control. Many are aging with inefficient processing lines and facility layouts prone to mechanical problems requiring manual interventions and thus are at higher risk for contamination. This high market concentration can turn a single production line disruption into a drug shortage.

Sterile injectables require a highly specialized manufacturing process. Production is often committed to specific production lines within those facilities because of the drug’s chemical properties, potential for cross contamination, and end product characteristics (e.g., vial size or whether a syringe is filled rather than a vial); and little or no redundant manufacturing capability is in place. If a production line dedicated to a cytotoxic chemotherapy drug becomes disabled or must be taken out of production, a ripple effect for shortages of other chemotherapy drugs produced in that facility can occur.⁷ Other manufacturing lines may produce multiple products in a continuous fashion (24/7) with little or no margin for error. When new generic product opportunities become available as occurred in 2008-2011 when several blockbuster drugs went off patent, trade-offs in production sometimes become necessary.

The best solution for this set of circumstances is upgraded and expanded manufacturing capacity. Given the current manufacturing environment, this can only be accomplished by having manufacturers go through this process in a way that is responsive to any required remediation, accomplishes upgrades to existing production lines, and incorporates construction of entirely new facilities while simultaneously manufacturing an array of finished products. While new and upgraded capacity is being established, manufacturing conditions that will allow for more stable supplies of sterile injectables are still at least a few years away.

CURRENT ACTIVITIES

FDA Drug Shortage Program

The FDA's drug shortage program resides with the Center for Drug Evaluation and Research. Eleven full-time staff work to help prevent and resolve acute shortages by working in a collaborative fashion with others in the FDA, other government agencies, manufacturers, and the public. The FDA also is collaborating on more widespread system solutions by working with various stakeholders including the Generic Pharmaceutical Association (GPhA), the Pharmaceutical Research Manufacturers of America, and the Biotechnology Industry Organization.

The FDA's primary "toolbox" for mitigating drug shortages includes:

- the use of regulatory discretion that allows for the continued manufacture of a medically necessary product when minor, low risk issues are identified, or the application of additional safety controls (i.e., extra testing at plant, 3rd party oversight of production, special instructions for safe use);
- requesting other manufacturers to increase production;
- expedited review of company proposals and applications; and,
- temporary importation from unapproved sources.

FDA Task Force on Drug Shortages

Consistent with AMA Policy H-100.956, FDASIA required the FDA to form an internal drug shortages task force to develop and implement a strategic plan for preventing and mitigating drug shortages.² As part of this process, the FDA issued a notice and request for comments to assist the agency in developing and implementing this plan; the AMA submitted formal comments on the proposal.

The strategic plan must include:

- plans for enhanced interagency and intra-agency coordination;
- plans for ensuring that drug shortages are considered when the Secretary initiates a regulatory action that could precipitate a drug shortage or exacerbate an existing drug shortage;
- plans for effective communication with outside stakeholders, including whom the Secretary should alert about potential or actual drug shortages, how the communication should occur, and what types of information should be shared;
- plans for considering the impact of drug shortages on research and clinical trials; and,
- an examination of whether to establish a "qualified manufacturing partner program," as described in section 506D(a)(1)(C) of the FD&C Act.

In its request for public comment, the FDA solicited input⁸ on several topics, including:

(1) how to encourage high quality manufacturing and expansion of capacity; (2) incentives that federal agencies, including the FDA, could offer to help prevent shortages; (3) how to best use existing tools or consider other actions that the FDA can take under its existing authority to address impending shortages; (4) tools the FDA should be using to manage communications to help alleviate potential or actual shortages, including the current public shortage Web site; (5) the impact of drug and biological shortages on research and clinical trials and what FDA can do to mitigate such impacts; and, (6) other actions or activities the FDA should consider including in the strategic plan to help prevent or mitigate shortages.

The strategic plan is scheduled to be completed by July 2013; a final rule implementing the plan is due by January 2014.

Generic Pharmaceutical Association

Given that the bulk of drug shortages involve generic sterile injectables, the GPhA proposed an innovative voluntary approach to identify shortages and craft a unified response addressing shortages from the production side. Under the Accelerated Recovery Initiative (ARI), generic companies will share manufacturing information about drugs in short supply with FDA through a third-party (IMS Health); as of April 19, 2013, five companies had agreed to participate. ARI seeks to provide FDA with information that GPhA believes will enable agency staff to more efficiently and

effectively accelerate the recovery of critical drugs in short supply. ARI is predicated on voluntary, confidential communication between IMS Health and pharmaceutical companies involved in the manufacturing of generic injectable drugs in shortage, a process which has been given the go-ahead by the Federal Trade Commission. A pilot version of this program is reportedly near launch. FDA and GPhA are currently working to identify four to eight products (all sterile injectables) that have at least two manufacturers who could cooperate in meeting market production needs. In addition, a multi-stakeholder approach involving participation from wholesalers, distributors, group purchasing organizations and the FDA will provide information that will be critical in assuring a focus on real-time decisions.

Medicare Part B Pricing

The basis for reimbursement for products covered under Medicare Part B changed under the Medicare Modernization Act of 2003 from Average Wholesale Price to Average Sales Price (ASP). Some have postulated that lower reimbursement to providers in turn puts more price pressure on generic manufacturers. One element of the “Patient Access to Drugs in Shortage Act” (as introduced) would change the Medicare reimbursement rate for sterile generic injectable products with 3 or fewer active manufacturers from ASP + 6% to the Wholesale Acquisition Cost (WAC) in order to achieve market price stability. However, the ASP reimbursement formula may be targeted during the federal budgeting process to an even lower percentage. ASP is the weighted average of all non-federal sales to wholesalers net of chargebacks, discounts, rebates, and other benefits tied to the purchase of the drug product, whether it is paid to the wholesaler or the retailer. WAC is developed by manufacturers using algorithms to account for expected demand for the product, future competition for the product and project marketing costs. The WAC is the baseline price at which wholesale distributors purchase products.

In any event, it is not the manufacturers who are being reimbursed. However, the prices that Group Purchasing Organizations try to negotiate for pharmaceutical products are under constant downward pressure from hospital members, who must adjust to declining revenues and reimbursement rates. The overall impact of these dynamics on shortages is unclear, and disagreement persists on whether the change in Medicare reimbursement is a driving force in drug shortages, especially in the case of chemotherapy drugs. Trends in shortages of drugs affected by the Medicare Part B formula are similar to the pattern among drugs that should not be affected by it.⁹ The GAO report is expected to more closely examine this issue, along with other economic variables.

COMMENT

Drug shortages continue to be a significant problem for hospitals, ambulatory care centers, physicians and their patients. Some improvement in the number of new shortages affecting “medically necessary drugs” is apparent although the overall number of shortages remains elevated. The majority of drug shortages are due to manufacturing quality issues, often related to aging infrastructure or production equipment. High market concentration of manufacturers and limited spare production capacity contribute to scenarios promoting drug shortages. Although the exercise of regulatory discretion by the FDA has been beneficial in mitigating individual drug shortages, this approach will not be as effective as company-based improvements in infrastructure, processes, and manufacturing lines. It also may paradoxically delay necessary upgrades if companies are able to temporarily cope from incident to incident with the help of dedicated FDA assistance.

Some new efforts are underway. The upcoming GAO report is designed to shed more light on the real world causes of drug shortages, including market driven and economic variables, and to recommend solutions in light of root cause analysis. A more comprehensive and dedicated strategic plan for mitigating and resolving drug shortages will be forthcoming from the FDA. The GPhA’s voluntary Accelerated Recovery Initiative shows promise for crafting real time, market-based solutions for a limited number of high profile, sterile injectables. The issue of incentives for manufacturers to upgrade facilities and expand production capacity, or to enter the market in the first place, is worth considering. Additionally, creation of a qualified manufacturing partner program is worth evaluating. The latter, perhaps modeled after the Biomedical Advanced Research and Development Authority, which coordinates the development and provides end-stage funding for products to be stored in a national stockpile and used as medical countermeasures, may have the potential to introduce redundancy and bolster supplies for a limited list of products. However, several barriers exist to this approach including the sheer number of shortages, lack of excess production capacity, and no suitable funding infrastructure for this type of approach.

In the meantime, additional resources intended for the FDA from the Generic Drug User Fee Act have the potential to expedite application reviews and inspections. FDA also should work to improve communication about existing drug shortages in a transparent fashion in order to promote confidence in their entire process.

Given the ongoing nature and clinical implications of drug shortages in the US, it is important that this issue be closely monitored and that our AMA continues to work to prevent and mitigate drug shortages and educate its members on this issue.

RECOMMENDATIONS

The Council recommends that the following statement be adopted and the remainder of the report be filed.

That Policy H-100.956(6 and 7) be amended to read as follows:

6. The Council on Science and Public Health ~~will~~ should continue to evaluate the drug shortage issue and report back on progress made in addressing drug shortages as appropriate. ~~at the 2013 annual meeting of the house of delegates.~~
7. Our AMA urges the development of a comprehensive independent report on the root causes of drug shortages. Such an analysis should consider federal actions, the number of manufacturers, economic factors, including federal reimbursement practices, as well as contracting practices by market participants on competition, access to drugs, and pricing. The Council should monitor and evaluate the forthcoming report on drug shortages from the Government Accountability Office and report back on its findings.

PROPOSED AMENDMENT REFERRED

The following proposed amendment to Policy H-100.956 was referred:

Our AMA advocate for government stockpiling of oral and parenteral drug shortage products or for removal of government policy price controls to mitigate against an unfair manufacturing free marketplace.

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9. Jacobson M, Alpert A, Duart F. Prescription drug shortages: reconsidering the role of Medicare payment policies. Health Affairs blog, 2012 (May 29) <http://healthaffairs.org/blog/2012/05/29/prescription-drug-shortages-reconsidering-the-role-of-medicare-payment-policies/>. (Accessed March 10, 2013)

9. PHARMACY COMPOUNDING

Reference committee hearing: see report of [Reference Committee E](#).

HOUSE ACTION: RECOMMENDATIONS ADOPTED AS FOLLOWS AND REMAINDER OF REPORT FILED

See Policy [H-120.945](#)

INTRODUCTION

Definition and Practice

Pharmacy compounding involves the preparation of customized medications that are not commercially available for individual patients with specialized medical needs.¹ Traditional pharmacy compounding involves the act of combining, mixing, or altering ingredients to prepare a customized medication for an individual patient upon receipt of a valid prescription for the compounded product. Driven by medical needs, cost issues, physician preferences, and in some cases drug shortages, the compounding industry has evolved over the past 20 years to include high capacity, industrialized practices involving batch production. Such products often enter interstate commerce and are delivered to health care settings in the absence of a specific patient prescription.

Patient Harm from Pharmacy Compounding

Several different surveys conducted by the US Food and Drug Administration (FDA) and state boards of pharmacy have identified serious quality issues with compounded drugs, most commonly clinically significant potency variations, but also lack of appropriate sterility testing.²⁻¹¹ Although the recent nationwide epidemic of fungal meningitis attributed to contaminated, preservative-free, compounded methylprednisolone injections focused attention on compounding practices, patient harm, including fatalities from compounded medications, is not new.¹² The Pew Charitable Trusts' Drug Safety Project has compiled a historical list of illnesses and deaths associated with compounded medications (also see testimony provided by FDA Commissioner Margaret Hamburg, MD, on this topic).^{13,14} According to Pew, since 2001 at least 20 pharmacy compounding errors have been associated with 1,022 adverse events, including 80 deaths. Contamination of sterile products was the most common compounding error, though some incidents were the result of miscalculations and mistakes in filling prescriptions. Examples include bacterial contamination of steroid injections and parenteral nutrition products, contaminated cardioplegia solutions or ophthalmic drug products, and superpotent intravenous colchicine solutions.² Recently, an outbreak of fungal endophthalmitis after intravitreal injection of repackaged bevacizumab (Avastin®) and triamcinolone was reported affecting 8 patients who suffered loss of visual acuity.¹⁵

Given the evolution of the pharmacy compounding industry, the current reliance of the healthcare system in this country on compounded drug products, and the accumulation of patient harm, the Council believes a clear need exists for more effective and appropriate oversight. This report also is responsive to American Medical Association (AMA) Policy D-120.949, "Ensuring the Safe and Appropriate Use of Compounded Medications," which directs the AMA to monitor ongoing federal and state evaluations and investigations of the practices of compounding pharmacies, encourage the development of regulations that ensure safe compounding practices that meet patient and physician needs, and report back on efforts to establish the necessary and appropriate regulatory oversight of compounding pharmacy practices. Accordingly, this report provides an overview of contemporary issues in pharmacy compounding and recommends amendments to existing AMA policy on this topic.

METHODS

English-language reports were selected from a PubMed and Google Scholar search from 2000 to May 2013, using the terms "pharmac*" in combination with "drug compounding/standards," "legislation/regulation," "oversight," and "epidemiology." Additional articles were identified by manual review of the references cited in these publications. Further information was obtained from the Internet sites of the US Food and Drug Administration (FDA), American Society of Health-System Pharmacists (ASHP), National Association of Boards of Pharmacy (NABP), and Centers for Disease Control and Prevention (CDC). Information also was derived from an invitational meeting on pharmacy compounding organized by ASHP, the Pew Charitable Trusts' Drug Safety Project, and the American Hospital Association.

CURRENT PHARMACY COMPOUNDING PRACTICES

In contrast to FDA-approved drugs, pharmacy compounded products are not evaluated for safety and efficacy, can be exempt from current good manufacturing practice requirements (cGMP), and lack standard product labels and instructions for safe use. Compounding pharmacies also are not required to report adverse events to the FDA. Nevertheless, despite the fact that all compounded products are viewed by the FDA as “unapproved drugs,” their availability has become an integral part of the daily practice of medicine and pharmacy in this country. The current “market” for pharmacy compounding comprises a diverse array of practices, some of which overlap, as follows:

Traditional Compounding

Tradition compounding is the practice of compounding a product for an individual patient pursuant to a valid prescription for the compounded product.

Anticipatory Compounding

Anticipatory compounding is the practice of compounding a product in batches before the receipt of a valid patient-specific prescription, often based on historical patterns of use. This practice should be distinguished from compounding in batches to fill orders from hospitals or other health care providers without any prescription. The latter practice, which usually relies on the use of specific vendors, comprises a portion of a hospital’s typical outsourcing activities (see below) and the provision of readily available “office stock” for clinicians.

Hospital Pharmacy-Based Compounding

Hospital pharmacies accomplish their own compounding of sterile infusions, solutions, injections, and pre-loaded syringes, as well as certain oral or topical products.

Hospital Outsourcing of Sterile Compounding Services.

Hospitals (as well as ambulatory clinics, surgical centers, and skilled nursing facilities) outsource orders for sterile compounded products. A portion of this practice is patient-specific, but most is done without a patient-specific prescription. Patient-specific compounded products are important in infectious disease, cardiology, immunosuppression, pain management, chemotherapy, fluid and electrolyte balance, required dilutions (e.g., pediatrics), allergy products, treatment of ocular diseases (topical, intravitreal, intraocular), pulmonary disease (inhalations), and certain irrigations. The typical scope of outsourcing includes pre-filled syringes (dilutions) for the operating room, epidural injections, opioid-based solutions for infusion pumps, pediatric electrolytes, concentrates (e.g., opioid and cardioplegia solutions), oxytocin infusions, some repackaged products, and products that may be unavailable due to drug shortages. The product array is driven to some degree by physician preferences. The trend toward increased outsourcing is based on sterility and quality assurance concerns, the need for standardization and availability of critical medications, pharmacy workload constraints, and lack of adequate facilities in-house.

Extent of Outsourcing. A survey of acute care hospitals participating in Medicare by the Office of Inspector General found that 92% of such hospitals relied on compounded sterile products.¹⁶ Although 25% of these hospitals also used higher risk compounded products (e.g., the use of nonsterile ingredients or devices with the intent of compounding sterile end products), such products comprised less than 1% of compounded sterile products that were used in 2012. Of the hospitals that used higher risk compounded sterile products in 2012, 85% purchased these products from outside sources.

Compounding “Manufacturers”

Although not strictly a defined class (as of yet), it is generally agreed that compounding “manufacturers” are entities which compound sterile products in bulk in the absence of a patient specific prescription. Batches are used for “off the shelf” marketing and distribution to supply clients such as hospitals, ambulatory care centers, clinics, skilled nursing facilities, and physician offices.

CURRENT COMPOUNDING STANDARDS

All states license pharmacists to compound, but states have varying degrees of regulation, oversight, and enforcement activities for compounding pharmacies. ASHP has published Technical Assistance Bulletins and Guidelines, for example, on the “Quality Assurance for Pharmacy-Prepared Sterile Products,” and “Guidelines on Outsourcing Sterile Compounding Services.”^{17,18} Other resources and training for sterile compounding also exist, and various state pharmacy practice acts create their own regulatory frameworks.

United States Pharmacopeia Standards

The United States Pharmacopeia Convention (USP), publisher of the United States Pharmacopeia and the National Formulary (USP–NF), the official compendia for drugs marketed in the United States, developed a set of enforceable compounding standards for practice. The primary USP standards on compounding are contained in two general chapters from USP-NF; <795> Pharmaceutical Compounding–Nonsterile Preparations and <797> Pharmaceutical Compounding–Sterile Preparations.^{19,20} In addition to these chapters, USP develops monographs that delineate standards for active pharmaceutical ingredients that may be compounded. The general chapters on compounding are supported by several other general chapters in USP-NF that address calculations, quality assurance, sterility tests, dosage forms, etc. A compilation of all general chapters relevant to compounding is available from USP via subscription or purchase.

USP-NF General Chapter <797> first became effective in 2004. Revised in 2008, it is currently undergoing further revision. The chapter is intended to promote practices for compounded sterile products that prevent harm to patients that could result from microbial contamination, endotoxins, incorrect strength, or unintended chemical or physical contamination of such products. This chapter applies to all practice settings where compounded sterile products are prepared and stored and identifies three risk levels for sterile compounded products, as follows:

High Risk

The highest risk is present when nonsterile ingredients or devices are used, and/or a product requires terminal sterilization. Examples include infusion pump solutions or epidural injections created from bulk powdered ingredients. High risk products should be used within 24 hours of preparation if stored at room temperature, or within 3 days if refrigerated, unless sterility testing is conducted to support extended labeling.

Medium risk

A medium risk for contamination would apply when multiple individual or small doses of sterile products are combined or pooled to prepare a compounded sterile product that will be administered either to multiple patients or to one patient on multiple occasions. Medium risk also exists when the compounding process includes complex aseptic manipulations or is of unusually long duration. One example is the compounding of total parenteral nutrition fluids (using manual or automated devices) during which there are multiple injections, detachments, and attachments of nutrient sources to a final sterile container. Another example would be filling the reservoirs of injection and infusion devices with more than three sterile drug products and evacuating air before the filled device is dispensed.

Low risk

The lowest risk for sterile compounding involves practices such as the single volume transfer of sterile dosage forms using sterile devices, or the simple aseptic measuring and transferring of ≤ 3 packages of sterile products to compound drug admixtures and nutritional solutions.

It should be noted that although Chapter <797> incorporates a number of core standards for training, facility design, labeling, and quality control and includes some suggested standard operating procedures for sterile compounding, it is not a substitute for, or equivalent to, cGMP required by the FDA for pharmaceutical manufacturers. The latter are process-directed and based on a system of specific standard operating procedures that the Agency evaluates for adherence to, within the manufacturer’s quality control system. The standards contained in USP-NF General Chapter <797> are generally most applicable to the compounding of sterile products in small batches.

State Boards of Pharmacy and USP Compounding Standards

As of January 2012, 18 state boards of pharmacy required compliance with USP <797>, 27 states and the District of Columbia have incorporated only selected portions or do not cite the chapter, but have regulations in place addressing sterile compounding or parenteral nutrition, and five states lack any mention of USP <797> and have no regulations on sterile compounding.²¹

REGULATION AND ACCREDITATION OF COMPOUNDING PHARMACIES

States

Compounding pharmacies are licensed and regulated by their respective state boards of pharmacy. As noted above, some states require adherence to USP standards, while others rely on their own regulatory standards.

In an effort to improve standards, the Pharmacy Compounding Accreditation Board (PCAB) was created in 2006 through the combined efforts of several national pharmacy organizations and USP.²² The mission of PCAB is to promote high quality pharmacy compounding through a voluntary accreditation program that recognizes adherence to established principles, policies and standards. PCAB accreditation gives patients, prescribers, and payers a way to select a pharmacy that meets or exceeds USP's quality standards. PCAB accreditation means the pharmacy has independent, external validation that it meets nationally accepted quality assurance, quality control, and quality improvement standards. However, only about 200 compounding pharmacies are currently accredited out of an estimated total of 7,000. A searchable state-by-state listing of accredited compounding pharmacies is maintained on the PCAB website.

Federal

The FDA has long been concerned about pharmacy compounding practices that deviate from the traditional model. The FDA first issued a Compliance Policy Guide (CPG) in 1992 that described certain factors that the Agency would consider in its enforcement approach to pharmacies that were producing drugs and appeared to be functioning more as manufacturers. That CPG remained in effect until Congress enacted the Food and Drug Administration Modernization Act of 1997. This legislation added a new Section 503A to the Food Drug and Cosmetic (FD&C) Act addressing FDA's authority over compounded drugs.²³ In doing so, Section 503A exempted compounded products from new drug approval, cGMP requirements, and adequate directions for use requirements under certain circumstances, and set forth conditions that must be followed by pharmacies or physicians in order to qualify for these exemptions. Among other things, the statute also included a requirement for a patient specific prescription for compounded products, prohibited advertising or promoting, and "compounding regularly or in inordinate amounts any drug products that are essentially copies of a commercially available drug product."

Before the law took effect, compounding pharmacies sued to block its implementation. In *Thompson v. Western States Medical Center* (535 U.S. 357, 2002), the United States Supreme Court held that congressional restriction of advertising and promotion by compounding pharmacies was unconstitutional. However, the Court did not rule on whether that advertising and promotion provision was "severable" from the rest of Section 503A. Federal circuit courts of appeals' decisions on this question are split. The 9th Circuit (including several western states and territories) holds that the provisions are not severable and hence Section 503A is considered void in its entirety; the 5th Circuit (several southwestern states) holds that the provisions are severable, and hence the remainder of Section 503A remains valid and enforceable.

Accordingly, different federal law exists for FDA authority depending on where the compounding pharmacy is located. It should be noted that the FDA revised the CPG in 2002 after the decisions from the US Supreme Court and Ninth Circuit, but before the decision of the Fifth Circuit, and without the advertising and interstate shipment provisions. The CPG articulates nine factors that the Agency would consider in their federal oversight capacity (see Appendix).²⁴ In weighing their determination, the FDA considers whether the prescribing practitioner has determined that a compounded product is necessary for the particular patient and would provide a significant difference, as compared with the FDA-approved commercially available drug product.

The FDA also can conduct "for-cause" inspections based on complaints. In the wake of the fungal meningitis outbreak, the FDA identified 31 compounding pharmacies engaging in sterile compounding practices for focused

priority inspections.¹⁴ Virtually all facilities had significant objectionable conditions and quality concerns and were issued form FDA-483.²⁵ This form does not constitute a final Agency determination of whether any condition is in violation of the FD&C Act, but the observations often serve as evidence of a violation of the Act and its implementing regulations. Some additional recalls of compounded products or safety alerts have subsequently occurred.

RISK-BASED APPROACHES TO REGULATION AND OVERSIGHT

USP General Chapter <797> identifies categories of risk based on process (i.e., sterile-to-sterile or nonsterile-to-sterile, and the number of product manipulations required or need for end-product sterilization). The degree of risk is inherent with the product type. Manipulation of sterile FDA-approved products is much less risky than starting with nonsterile active pharmaceutical ingredients and attempting to compound a sterile injectable product.

Some risk factors are common to both patient specific and batch compounding such as facility characteristics, personnel training, level of standardization, verification mechanisms, and compliance with standard operating procedures. For patient-specific compounding, beyond use dating and storage outside of the pharmacy also need to be addressed. For sterile batch compounding, standard operating procedures, segregation of materials, batch sizes, in-process checks, and sterilization methods assume increasing importance. The larger the operation, the more closely these processes should be aligned with cGMP. Product quarantine, assurance of sterility, and recall mechanisms are necessary requirements for compounding manufacturers, not to mention assurance of batch potency. Product volume and whether the facility attempts to generate product beyond its capabilities or to fill a temporary gap created by commercial drug shortages represent other categories of risk. Finally, distribution, storage, and repackaging practices also are relevant.

CURRENT LEGISLATION

According to the National Conference of State Legislatures, several states have introduced bills related to the regulation of compounding pharmacies. One issue is potential limits on office-use dispensing, or the practice of physicians obtaining compounded products without a patient prescription to be used in an office setting. At the state level, interest is moving in the direction of regular inspections, composition of state boards to include the relevant expertise for addressing sterile compounding issues, and more widespread adoption of USP standards for sterile compounding.

In early May, bipartisan legislation intended to clarify oversight for pharmaceutical compounding was introduced in the Senate (S. 959—Pharmaceutical Compounding Quality and Accountability Act). This goal of this legislation is to establish a clear boundary between traditional compounders and compounding manufacturers, and establish uniform federal quality standards for compounding manufacturers. Compounding manufacturers are defined as entities that (1) compound a sterile product prior to or without receiving a prescription (or that repackage a drug using sterile, preservative-free single dose vials, or that pool any sterile drug product) and, (2) introduce such drugs into interstate commerce. Interstate shipment of sterile compounded products produced by a hospital pharmacy within a self-contained hospital system would be exempted from this definition, and would be regulated as traditional compounding. Compounding manufacturers would not be licensed as state pharmacies and would have to register with the FDA (for a fee), provide a list of their products, operate in compliance with cGMP, investigate and report adverse events, and properly label products.

The legislation also prohibits the compounding of certain categories of drugs. It also preserves the state's primary role in the oversight of traditional pharmacy compounding, and permits limited quantities of products derived from anticipatory compounding, although biologics would be excluded from this practice, except in narrow circumstances (i.e., pediatric use within a hospital setting). The AMA submitted formal comments on the draft legislation, but it is not clear at this time how quickly this bill will move or what the final elements will be.

AMA POLICY

Current AMA Policy H-120.945, "AMA Action on Non FDA-Approved Compounded Medications," recognizes that compounding pharmacies should comply with current USP-NF compounding monographs, when available, and recommends that they be required to conform with USP-NF General Chapters on pharmaceutical compounding to ensure the uniformity, quality, and safety of compounded medications. AMA policy also recognizes the value of the

PCAB accreditation program and encourages all state boards of pharmacy to require compounding pharmacies in their states to obtain the PCAB™ Seal of Accreditation or, alternatively, to satisfy comparable standards that have been promulgated by the state in its laws and regulations governing pharmacy practice. Finally, AMA policy encourages state boards of pharmacy and the NABP to work with the FDA to identify and take appropriate enforcement action against entities that are “illegally” manufacturing medications under the guise of pharmacy compounding.

COMMENT

While traditional compounding pharmacies licensed and regulated by states continue to provide important patient-specific services, the overall practice of pharmacy compounding has evolved into an industrial-scale national business. A need exists to establish a clear boundary between traditional compounders and compounding manufacturers and to clarify specific areas of jurisdiction for the FDA and state boards of pharmacy. Because of the extensive array of current pharmacy compounding practices, and dependence of the healthcare system on such products, changes to the current system must be accomplished in a stepwise manner and in a way that does not otherwise jeopardize patient care. In the absence of a suitable FDA-approved product, allowances also must be made for compounding practices that can realistically supply products needed to manage urgent and emergency situations in individual patients.

RECOMMENDATION

The Council recommends that the following statement be adopted and the remainder of the report be filed.

That Policy H-120.945, “AMA Action on Non FDA-Approved Compounded Medications,” be amended to read as follows:

Our AMA: 1. recognizes that traditional compounding pharmacies must be subject to state board of pharmacy oversight and comply with current United States Pharmacopeia and National Formulary (USP-NF) compounding monographs, when available, and recommends that they be required to conform with USP-NF General Chapters on pharmaceutical compounding to ensure the uniformity, quality, and safety of compounded medications; 2. ~~recognizes the accreditation program of the Pharmacy Compounding Accreditation Board (PCAB™) and the PCAB™ Seal of Accreditation as a means to identify compounding pharmacies that adhere to quality and practice standards, including those set forth in the USP-NF, for the preparation of individualized medications for specific patients;~~ 3. encourages all state boards of pharmacy to reference sterile compounding quality standards, including but not limited to those contained in United States Pharmacopeia Chapter <797>, as the standard for sterile compounding in their state ~~require compounding pharmacies in their states to obtain the PCAB™ Seal of Accreditation or, alternatively, and~~ to satisfy other relevant comparable standards that have been promulgated by the state in its laws and regulations governing pharmacy practice; ~~and~~ 3. supports the view that facilities (other than pharmacies within a health system that serve only other entities within that health system) that compound sterile drug products without receiving a prescription order prior to beginning compounding and introduce such compounded drugs into interstate commerce be recognized as compounding manufacturers subject to FDA oversight and regulation; 4. supports the view that allowances must be made for the conduct of compounding practices that can realistically supply compounded products to meet anticipated clinical needs, including urgent and emergency care scenarios, in a safe manner; and, 5. in the absence of new federal legislation affecting the oversight of compounding pharmacies, continues to encourages state boards of pharmacy and the National Association of Boards of Pharmacy (NABP), ~~the umbrella organization for state boards of pharmacy,~~ to work with the United States Food and Drug Administration (FDA) to identify and take appropriate enforcement action against entities that are illegally manufacturing medications under the guise of pharmacy compounding.

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APPENDIX – Compliance Policy Guidance for FDA Staff and Industry, Sec. 460.200 Pharmacy Compounding–Policy

Generally, FDA will continue to defer to state authorities regarding less significant violations of the Act related to pharmacy compounding of human drugs. FDA anticipates that, in such cases, cooperative efforts between the states and the Agency will result in coordinated investigations, referrals, and follow-up actions by the states. However, when the scope and nature of a pharmacy’s activities raise the kinds of concerns normally associated with a drug manufacturer and result in significant violations of the new drug, adulteration, or misbranding provisions of the Act, FDA has determined that it should seriously consider enforcement action. In determining whether to initiate such an action, the Agency will consider whether the pharmacy engages in any of the following acts:

1. Compounding of drugs in anticipation of receiving prescriptions, except in very limited quantities in relation to the amounts of drugs compounded after receiving valid prescriptions.
2. Compounding drugs that were withdrawn or removed from the market for safety reasons. Appendix A provides a list of such drugs that will be updated in the future, as appropriate.
3. Compounding finished drugs from bulk active ingredients that are not components of FDA approved drugs without an FDA sanctioned investigational new drug application (IND) in accordance with 21 U.S.C. § 355(i) and 21 CFR 312.

4. Receiving, storing, or using drug substances without first obtaining written assurance from the supplier that each lot of the drug substance has been made in an FDA-registered facility.
5. Receiving, storing, or using drug components not guaranteed or otherwise determined to meet official compendia requirements.
6. Using commercial scale manufacturing or testing equipment for compounding drug products.
7. Compounding drugs for third parties who resell to individual patients or offering compounded drug products at wholesale to other state licensed persons or commercial entities for resale.
8. Compounding drug products that are commercially available in the marketplace or that are essentially copies of commercially available FDA-approved drug products. In certain circumstances, it may be appropriate for a pharmacist to compound a small quantity of a drug that is only slightly different than an FDA-approved drug that is commercially available. In these circumstances, FDA will consider whether there is documentation of the medical need for the particular variation of the compound for the particular patient.
9. Failing to operate in conformance with applicable state law regulating the practice of pharmacy.