Fund the FOOD SAFETY Initiative

Vice President Al Gore called on Congress to fund the President's Food Safety Initiative after the Senate Appropriations Committee allocated just $2.6 million and the House allocated just $16.8 million—less than one-fifth of the Administration's request. He also urged state and local governments and consumers to do their part to make America's food safer.

This initiative calls for:

- giving the Food and Drug Administration (FDA) authority to prevent the import of produce from countries that lack safety precautions equivalent to our own;
- further expanding our early warning system and strengthening state surveillance activities for foodborne illness;
- hiring FDA inspectors to improve the safety of our nation's fruit and vegetables, both domestic and imported;
- developing new ways for Federal inspectors to detect foodborne illnesses in meat and poultry and determine the sources of contamination; and
- improving education outreach on proper food handling.

The Vice President encouraged state and local governments and the retail food industry to follow the food safety recommendations in the FDA's Food Code—its recommended but voluntary standards and practices to keep food safe in restaurants, grocery stores, nursing homes, day care centers, and in other local food service operations.

In addition, the Vice President called on Congress to pass the Food Safety and Enforcement Enhancement Act, sponsored by Sen. Tom Harkin (D-IA), which would enable the Department of Agriculture to assess civil fines and order mandatory recalls of unsafe meat and poultry products. ■

NATIONAL COMPUTER NETWORK TO COMBAT FOODBORNE ILLNESS

In 1993, investigators searched for weeks to locate the common food source of an unexplained outbreak of gastrointestinal disease. Ultimately, hamburgers served at a large chain of regional fast food restaurants proved to be the culprit. Today with the launch of a national computer network of public health laboratories, PulseNet, epidemiologists can quickly detect whether illnesses occurring in many different locations during the same time frame are linked to a common food source.

PulseNet is based on a molecular technology called pulsed-field gel electrophoresis (PFGE), first used by the Centers for Disease Control and Prevention (CDC) in 1993. The technology allows epidemiologists to identify distinctive "fingerprint" patterns of *E. coli O157:H7*, which helps epidemiologists to more quickly trace the source of a problem.

In 1995, CDC began to set up PulseNet with state public health laboratories in Massachusetts, Minnesota, Texas, and Washington, which are designated "area" laboratories and provide PulseNet services to states in their region. These area laboratories, as well as those of the Department of Agriculture (USDA) and the Food And Drug Administration (FDA), could link directly to the CDC computer server and gain direct access to the CDC database.

Other labs connected to PulseNet are in California, Colorado, Florida, Georgia, Iowa, New Hampshire, New York, Ohio, Oregon, Utah, Virginia, and Wisconsin. ■

FDA Study Finds Test Kits Effective in Spotting Birth Defects

Findings from a 10-year study directed by the Food and Drug Administration (FDA) suggest that alpha-fetoprotein (AFP) testing with a kit is a more effective way to identify pregnant women potentially at risk of carrying a fetus with neural tube defects (NTDs) such as anencephaly and spina bifida than other choices available. The kit provides a more accurate estimate of levels of AFP in maternal serum and amniotic fluid.

Results of the study conducted from 1984 to 1994 also point to the need for inclusion of all terminated pregnancies in any calculation of the prevalence of NTDs at birth, according to Kearby J. Fugate, PhD, coordinator of the study.

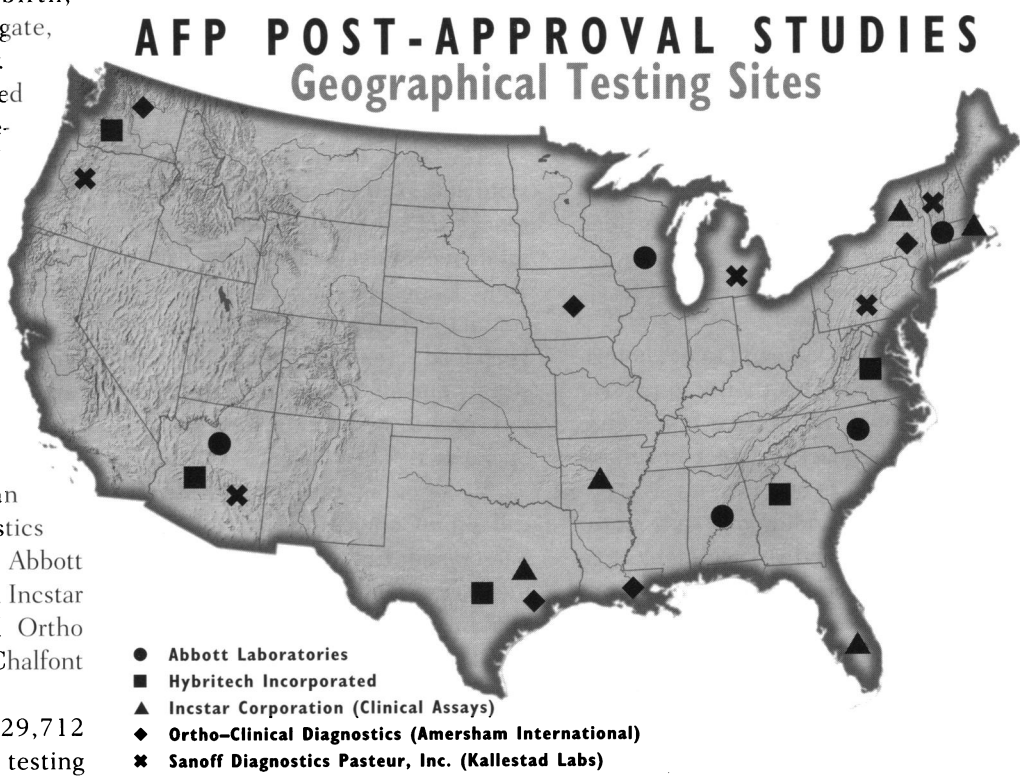
In 1984, the FDA approved the test kits. This study represents a collaborative effort of five manufacturers of the AFP test kits and the FDA. "We wanted to assess the performance characteristics of the kits and the epidemiologic impact of the testing on the prevalence of the neural tube defects," Fugate said. The five manufacturers were Hybritech, Inc., San Diego, CA; Sanofi Diagnostics Pasteur, Inc., Chaska, MN; Abbott Laboratories, Abbott Park, IL; Incstar Corp., Stillwater, MN; and Ortho Clinical Diagnostics, Ltd., Chalfont St. Giles, England.

Researchers enrolled 29,712 pregnant women from 25 testing centers (see map) for the maternal serum AFP (MSAFP) testing; complete information was obtained from 14,626 pregnancies. No selection criteria were applied. The median AFP value for each gestational week was first determined, then individual AFP levels were reported as multiple of the normative median.

All subjects with elevated MSAFP levels were provided with an ultrasound evaluation. If no reason for MSAFP elevation could be found, a second MSAFP was performed. Women with two elevated MSAFP results and a failure of ultrasound examination to identify the reason for the MSAFP elevation were given an amniocentesis with subsequent analysis of fluid for amniotic fluid alpha-fetoprotein (AFAFP). Both blood and amniotic fluid were tested to confirm findings.

The sensitivity of the MSAFP test was 91.7%, specificity 96.0%, and positive predictive value 3.6%. The AFAFP test of the amniotic fluid samples had a sensitivity of 100%, specificity of 98.0%, and positive predictive value of 73.1%. The prevalence of the NTDs (per 1000 pregnancies) was 1.64 (confidence interval 0.98, 2.30). Out of 24 pregnancies with an NTD outcome, six were carried to term, while 12 were terminated as elective abortions and six as spontaneous abortions.

More complete results of the study may be obtained from Kearby J. Fugate, FDA, 2098 Gaither Rd., Rockville, MD 20850; e-mail <kjf@cdrh.fda.gov/>. ■



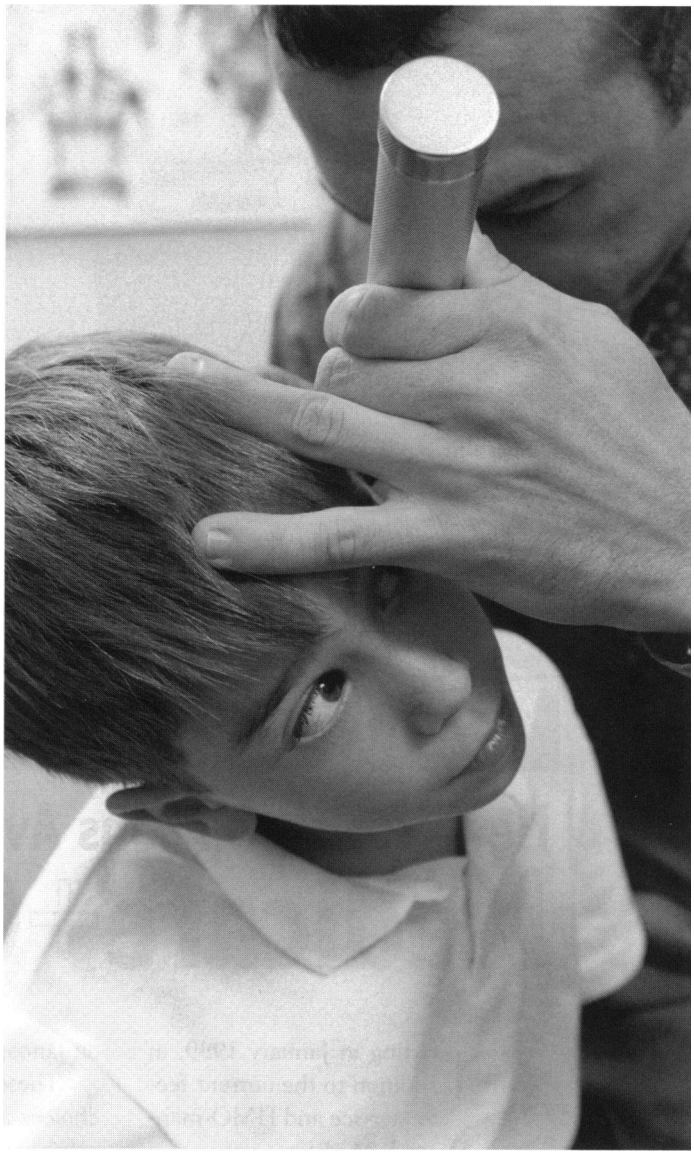
States Must Be Held Accountable for NEW HEALTH PLANS for Children

Last year, a five-year insurance expansion of $24 billion was passed as part of the Balanced Budget Act of 1997. It allocates $20.3 billion for states to use in expanding private insurance for children and another $3.6 billion to improve coverage under Medicaid. Although the states have been given great latitude under the act, they must apply for Federal funds through the Department of Health and Human Services (DHHS), which approves and funds each state's plan.

Two reports from a committee of the Institute of Medicine remind Congress and the Federal government that they need to take immediate steps to ensure that states are held accountable for meeting the goals of the new programs. *America's Children: Health Insurance and Access to Care* examines the relationship between children's health and access to care. A companion report, *Systems of Accountability: Implementing Children's Health Insurance Programs*, makes recommendations to state and Federal officials who are implementing the new and expanded insurance plans.

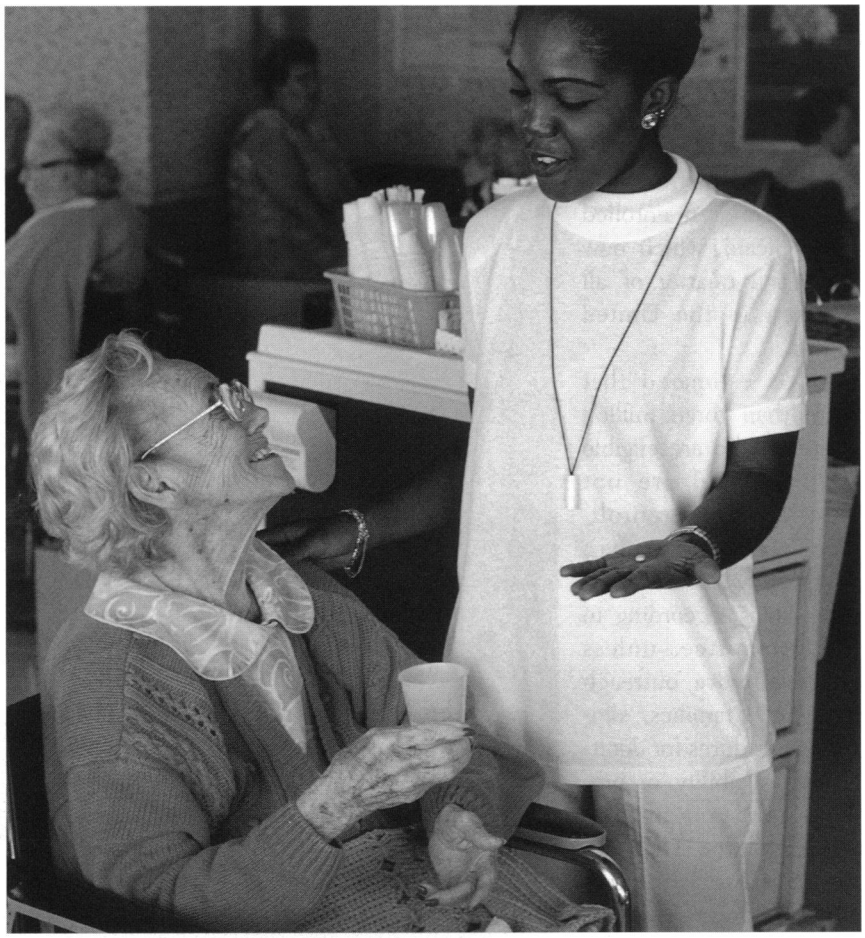
More than 11 million children, or one in seven, are estimated to be uninsured in the United States. Most are in families with working parents who have jobs that do not provide insurance and who cannot afford to buy it on their own. The problem has been exacerbated in the last decade by changes in the benefits that employers provide for their workers. The percentage of children who are covered by employer-based insurance has declined in the past decade; this decline has been partially offset by an increase in the number of children enrolled in Medicaid, which now reaches a quarter of all children in the United States.

It is estimated that more than three million children who are eligible for Medicaid are not enrolled. Underenrollment will continue to be a problem with the new state plans, according to the committee, unless states improve outreach to eligible families, simplify procedures for determining eligibility, or provide new programs to insure children. The committee also suggests that all state efforts should be designed to achieve the highest possible enrollment through coordination with other state and private programs to maximize children's opportunities to receive access to care. In addition, states should provide adequate reimbursement rates to maintain and improve provider participation and enforce quality standards for all providers.



The study was funded by the Robert Wood Johnson Foundation.

Copies of America's Children: Health Insurance and Access to Care *are available from the National Academy Press, 2101 Constitution Ave. NW, Washington DC 20418; tel. 202-334-3313 or 800-624-6242 for $45 (prepaid) plus shipping charges of $4 for the first copy and 50 cents for each additional copy. Copies of* Systems of Accountability: Implementing Children's Health Insurance Programs *are available free from the Division of Health Care Services; tel. 202-334-2184.* ■



New Health Options Available Under Medicare+Choice

Starting in January 1999, in addition to the current fee-for-service and HMO-managed Medicare options, a broader array of health plans will be able to join Medicare. These expanded health plan choices, known as Medicare+Choice, were created as part of the bipartisan Balanced Budget Act of 1997. Risk HMOs that already contract to enroll Medicare beneficiaries will be eligible to become Medicare+Choice plans on January 1, 1999.

These options will increase the choices available to Medicare beneficiaries, particularly in rural areas. Currently, 17% of Medicare beneficiaries are in managed care plans. It is expected that by 2005, approximately 30% of all Medicare beneficiaries will be enrolled in Medicare+Choice plans. Access to Medicare+Choice options will depend on where the beneficiary lives and what types of plans are available in that community.

DHHS has issued a regulation that describes policies and standards health plans and organizations must meet to participate in the Medicare+Choice program. The standards cover enrollment, benefits, access, beneficiary protections, quality assurance, provider protections, payments, premiums, and sanctions.

The options are: health maintenance organizations (HMOs), health maintenance organizations with a point-of-service (POS) option, preferred provider organizations (PPOs), provider-sponsored organizations (PSOs), private fee-for-service plans, and medical savings accounts (MSAs).

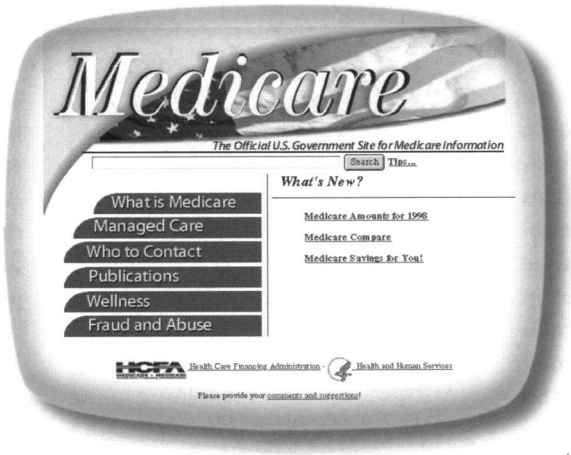
Congress has authorized up to 390,000 Medicare beneficiaries to participate in an MSA demonstration. Unlike in other Medicare+Choice options, individuals who enroll in MSAs are locked in for the entire year, with a one-time option of withdrawing by December 15 of the year in which they enrolled.

To assist Medicare beneficiaries in making decisions about their care, DHHS's Health Care Financing Administration (HCFA) is planning a comprehensive national information campaign, including a national website with comparative information on available plans (*see adjacent* News and Notes *item*). HCFA will also begin piloting in five states a toll-free hotline service to assist beneficiaries and continue focus group testing of a comprehensive Medicare handbook, *Medicare and You*. Beneficiaries will receive information this fall regarding the Medicare MSA demonstration project and other Medicare health plan options.

Although many Medicare beneficiaries will have a larger number of health plan options to choose from, no beneficiary is required to change the way he or she currently receives care. ■

HCFA Establishes Official Website for MEDICARE INFORMATION

Increasing numbers of Medicare beneficiaries use the Internet or have access to it through their families, friends, health care providers, or service organizations. A Merrill Lynch–sponsored survey conducted in September last year shows that 15% of those ages 65 and older use the Internet. And Packard Bell NEC Inc., has said that customers older than age 55 accounted for 14% of retail purchases of its personal computers in 1997. The American Association of Retired Persons reports that in 1997, 36% of Americans from ages 50 through 64 owned a personal computer.



Responding to this growing opportunity to provide beneficiaries with up-to-date information, the Health Care Financing Administration (HCFA) has created two new websites: **www.Medicare.gov** and **Medicare Compare.**

www.Medicare.gov offers a variety of useful and easy-to-read information about Medicare, including details of the new Medicare+Choice available under the Balanced Budget Act (*see previous* News and Notes *item*), including:

- *What is Medicare?* Answers to questions about Medicare, including eligibility requirements, how to enroll, and how to read a Medicare summary notice.
- *Managed Care.* New managed care options that will be available in 1999 as a part of the Medicare+Choice options.
- *Who to Contact.* State-specific contact information on a variety of Medicare topics including: receiving Medicare; understanding your Medicare bill; Medicare rights; benefits; dealing with complaints and appeals; and managed care.
- *Publications.* A variety of publications (in both English and Spanish) for viewing and printing.
- *Wellness.* Focuses on health issues such as peptic ulcers, pneumonia, and the flu and new Medicare prevention benefits.
- *Fraud and Abuse.* Describes common types of Medicare fraud and teaches how to report suspected fraud. A consumer fraud pamphlet is available to view and print.
- *Medicare Compare.* A link to this site (*see below*).

Medicare Compare is HCFA's new electronic database of information about accredited managed care plans that already serve nearly six million Medicare beneficiaries across the country. The database is designed to educate beneficiaries and others about their health care options so they can make informed choices. The information is compiled with cooperation from managed care plans and will be updated on a quarterly basis.

Medicare Compare contains toll-free telephone numbers and website addresses for health plans; service areas listed by state, zip code, and county so beneficiaries can compare services in their own geographic areas; benefit and service packages offered by each plan, including detailed information on premiums, copays, deductibles; "helpful hints" to help users navigate within the database; and guest book/e-mail link back to HCFA for users' comments, questions, and suggestions. Users can display side-by-side comparisons of services offered by two health plans and search for a specific type of service such as vision care or podiatric care.

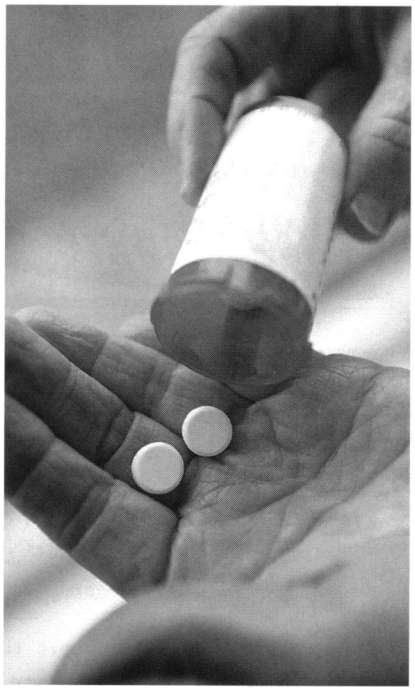
The URL for the site is **www.agenet.com/medicare_compare**. ■

Better Surveillance and More Awareness Needed To Deal With Rise in Antibiotic Resistance

Fighting the problem of antibiotic resistance will require a better, more coordinated system of surveillance as well as an increased effort to prolong the effectiveness of existing antibiotics, according to a report from the Institute of Medicine's (IOM) Forum on Emerging Infections. Widespread, inappropriate use of antibiotics has led to premature emergence of resistance. Increasing the useful lifetime of antibiotics will require changes in attitude and behavior among health care providers, patients, parents, managed care organizations, the pharmaceutical industry, and others.

IOM's Forum on Emerging Infections was created in response to a request from the Centers for Disease Control and Prevention (CDC) and the National Institute of Allergy and Infectious Diseases. The Forum brings together representatives from academia, industry, government, and professional and interest groups to examine and discuss scientific and policy issues related to emerging infections.

The report points out that current efforts to ensure proper antibiotic use consist primarily of trying to educate people about the hazards of antimicrobial overuse or misuse. While resistance is sometimes tracked across local, national, and international jurisdictions, these efforts are uncoordinated and lack common standards for data collection. An effective national surveillance program would allow broad access to information and data gathered from all parties, integrate information from participating laboratories into a national database, and distinguish cases of drug resistance occurring in hospitals from those found in the local community. Forum members believe that professional societies should collaborate to develop uniform guidelines that encourage better practices.



The report also points out that policymakers will need to decide whether the United Nations' World Health Organization or the CDC should lead a global surveillance effort.

More research is needed on the impact of antibiotic overuse and misuse on humans; on finding new ways to define a drug's effectiveness; and on the benefits and risks of reducing antimicrobial doses and duration of therapy. In addition to preserving the effectiveness of the current groups of antibiotics, incentives are needed to develop new drugs. Pharmaceutical industry representatives at the workshop felt that efforts need to be directed toward promoting and fostering joint ventures that meet the scientific, legal, and regulatory concerns of industry and academic institutions alike.

The IOM report also recommended further research in the area of the human health effects of widespread agricultural use of antibiotics. A separate study on the use of antibiotics in chicken, cattle, and other food animals and products and their potential impact on human health will be completed by the National Research Council later this year.

This project was funded by Abbott Laboratories; the American Society for Microbiology; Applied Microbiology Inc.; Bristol Myers Squibb; the Burroughs Wellcome Fund; the Centers for Disease Control and Prevention; Eli Lilly & Co.; F. Hoffmann-La Roche; the Food and Drug Administration; Glaxo Wellcome; Merck and Co. Inc.; the National Institute of Allergy and Infectious Diseases; Pfizer Inc.; SmithKline Beecham Corp.; the Department of State; the Department of Veterans Affairs; and Wyeth-Ayerst.

Copies of Antimicrobial Resistance: Issues and Options *are available from the National Academy Press, 2101 Constitution Ave. NW, Washington DC 20418; tel. 202-334-3313 or 800-624-6242 for $25 (prepaid) plus shipping charges of $4 for the first copy and 50 cents for each additional copy.* ■

Adverse Health Effects of ELECTROMAGNETIC FIELDS Still Being Discussed

The last 10 years have seen the rapid expansion of technologies generating electromagnetic fields. Mobile telephone technology, for example, has gone from being an executive toy to an indispensable part of modern communications. Concerns have been voiced in many countries about possible adverse health effects of these fields. Domestically, the U.S. government has appointed several committees to review research to date.

In recent months, public science symposia have reviewed laboratory findings and a theoretical mechanism of action (March 1997), epidemiology findings (January 1998), and in vivo and clinical studies (April 1998). These meetings were organized under the congressionally mandated Electric and Magnetic Fields Research and Public Information Dissemination Program (EMF/RAPID). Members of a working group composed of scientists with a broad range of expertise met in Brooklyn Park, Minnesota, in June to review the outcomes of the public symposia and other research in order to write an advisory report for the National Institute of Environmental Health Sciences (NIEHS).

The members' report will provide guidance to NIEHS on the strength of the experimental data and its implications for human health and disease etiology. NIEHS Director Kenneth Olden, PhD, will use the appraisals and working group review as well as other relevant information in formulating his own report to Congress later this year.

The draft of the working committee report may be commented upon in writing. The report and times and locations of additional public symposia are available at: tel. 919-541-7534; fax 919-541-0144; website ***www.niehs.nih.gov/emfrapid/home.htm.*** ■

FOOD & DRUGS FOR KIDS

The Food and Drug Administration (FDA) has developed the Kids' Home Page, a special Internet site designed to help children ages 9 through 12 learn more about the agency and its public health activities.

The site teaches boys and girls about FDA through games such as a medicine cabinet word find, a food safety quiz, an interactive human skeleton, and a pet care tips section.

The new website also offers a good starting point for older children and teenagers to research FDA-related subjects. It includes links to the "Teen Scene," a section of *FDA Consumer* magazine, as well as FDA's main website, and a Parent's Corner that links to *FDA Consumer* articles on child health and nutrition.

The FDA Kids' Home Page is at **www.fda.gov/oc/opacom/kids/.** ■