THE CANCER LETTER INTERACTIVE

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# NCI To Invite Unaffiliated Oncologists To Enroll Patients On Phase III Trials

After a five-year effort to redesign the cancer clinical trials system, NCI next week will allow U.S. and Canadian oncologists to enter patients on many of the phase III trials sponsored by the Institute.

Until now, enrollment privileges were limited to members of the cooperative groups.

By broadening access to trials, NCI implements a key recommendation of a 1997 report by an extramural commission which examined the clinical trials system as part of the redesign of the Institute

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*In Brief:*

## Johns Hopkins Oncology Center Renamed To Honor Sidney Kimmel For $150M Gift

**SIDNEY KIMMEL** Comprehensive Cancer Center at Johns Hopkins is the official name of the former Johns Hopkins Oncology Center. The center held a celebration May 4 officially renaming the center and honoring Kimmel and his $150 million gift to be used for cancer research, patient care, and a new patient and family pavilion. Kimmel, founder and chairman of Jones Apparel Group, has made donations to name two other centers before Hopkins: the Kimmel Cancer Center at Thomas Jefferson University in Philadelphia, and the Sidney Kimmel Cancer Center in San Diego. New York City Mayor **Michael Bloomberg**, chairman of the Johns Hopkins University Board of Trustees, ABC news correspondent **Sam Donaldson**, NCI Director **Andrew von Eschenbach**, and Maryland Gov. **Parris Glendening** were among the speakers at the dedication event. . . . **RODERIC PETTIGREW** was named the first director of the National Institute of Biomedical Imaging and Bioengineering. He is professor of radiology, medicine (cardiology) and bioengineering and director of the Emory Center for MR Research, Emory University School of Medicine. Pettigrew is known for his work in dynamic three-dimensional imaging of the heart using magnetic resonance. He also was co-developer of the first computer software package designed for cardiac imaging using MRI. NIBIB was established by Congress in December 2000. The mission of NIBIB is to improve health by supporting fundamental research in bioengineering and bioimaging science and transferring the results to medical applications. NIBIB awarded its first grants in April 2002. Pettigrew is expected to begin his appointment in

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## Designed To Boost Enrollment, CTSU Accrues 160 Patients

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by former Director Richard Klausner.

The central element of the revamped clinical trials system—the Clinical Trials Support Unit designed to make phase III trials more accessible to doctors—has been available to members of the cooperative groups for the past three years. Now, all oncologists will be invited to use CTSU.

The broadened access is scheduled to be announced during the annual meeting of the American Society of Clinical Oncology, in Orlando May 18-21. While NCI officials project that only a few dozen physicians will sign up, opening trials to oncologists not involved in the clinical research system may represent a political milestone in the Institute.

"This is not going to solve the problem of clinical trial accrual overnight," said Jeff Abrams, senior investigator in the NCI Cancer Therapy Evaluation Program. "We aren't going to get hundreds of non-group physicians. If we get 30 to 50, that would be good."

The CTSU is one of several pilot projects NCI developed in response to a report by a committee headed by oncologist James Armitage, of the University of Nebraska. The committee recommended greater flexibility and inclusiveness in the cancer clinical trials system. Also, the report called for greater participation in designing trials from basic and clinical scientists, community and research oncologists, and cancer survivors.

However, changing an entrenched, functioning system has proved to be difficult process, NCI officials acknowledge.

Intended to eliminate barriers that physicians described when trying to enter patients on trials, the CTSU provides oncologists with a single access point for selected phase III trials. The trials "menu" is a cross-group listing of all phase III trials in lung and genitourinary cancers, and most breast, gastrointestinal, and leukemia studies.

NCI funds the CTSU under a five-year, $50 million contract, now in its third year, with Westat Corp., of Rockville, MD. Westat has subcontracted a portion of the project to the Coalition of National Cancer Cooperative Groups, based in Philadelphia, and the Oracle Corp. Health Informatics Consulting Practice.

Currently, about 3,500 oncologists, out of a total of about 6,000 cooperative group members, have registered with the CTSU. So far, only 160 patients have been enrolled on trials. The CTSU provides $2,000 per patient, the same as the cooperative groups, but far less than most pharmaceutical company trials.

The accrual is disappointing, Abrams said. "We had hoped to be in the thousands by now, but a lot of the studies that were initially taken on by the CTSU weren't doing well in the groups, so it was no surprise they didn't do well in the CTSU, either," he said. "Now we are adding more popular trials. We hope accrual will pick up."

Three of the trials recently added were NSABP B-34, E4599, and SOO03.

An emphasis on bringing new investigators into the system may be misplaced, said Robert Comis, president of the Coalition of National Cancer Cooperative Groups and chairman of the Eastern Cooperative Oncology Group.

Though Comis is a subcontractor on the CTSU, he gives the new move to open studies to non-group oncologists lukewarm praise.

"I think it's an interesting new step," Comis said. "One would hope that opening it up to more doctors might result in more accrual."

Comis noted that the cooperative groups accrued 27,000 patients to clinical trials in 2001, up 30 percent from the previous year. Part of the reason for increased accrual was NCI's increase in per-

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patient reimbursement from $1,500 to $2,000.

"The doctors who are interested are already engaged, but their level of participation is low," Comis said.

A study by the American Society of Clinical Oncology found that it costs oncologists about $3,000 to $3,500 to enroll patients on trials. "Every time a doctor enrolls someone on an NCI study, the lose $1,000 or more," Comis said. By contrast, pharmaceutical companies pay $5,000 to $6,000 per patient.

"I don't object to trying a new strategy, but if we helped the doctors who are already involved, and tried to make it more resource-neutral for them, it would be better," Comis said.

NCI official Abrams said the CTSU will achieve its purpose if it encourages lower-accruing group members to enroll more patients, by simplifying access to trials. Generally, about one-third of group members accrue the majority of patients to trials, Abrams said. "If we can help the oncologist who puts five patients on trials a year to put 10 patients on trials a year, then we'll accrue trials faster and get answers sooner," Abrams said.

Besides the access to phase III cooperative group studies, Abrams said the benefits for a non-group physicians of joining the CTSU include: no requirement for meeting a minimum accrual target, and access to the CTSU Web site for protocols, informed consent forms, case report forms, the IRB submission package, and patient education materials.

"Our selling point is that we feel we are doing high-quality research with a level of peer review that is unsurpassed," Abrams said. "We hope it will be a more efficient system, as well, with standardized forms and requirements."

Oncologists interested in signing up with the CTSU will have to meet requirements for involvement in research, such as having access to an Institutional Review Board and appropriate staff.

For group members, the CTSU trials provide credit toward group membership, and investigators only need to register once for all groups.

**Central IRB Reviews Phase III Protocols**

The CTSU also provides Central IRB review of its phase III trials, another NCI initiative designed to address the overwork and backlog being experienced by many local IRBs. The CIRB has been meeting monthly since January 2001 and reviews 30 to 40 phase III adult cooperative group protocols a year.

The CIRB has reviewed 19 protocols since its inception and approved 17. Two protocols were not approved initially, and three more are scheduled for review.

Currently, 22 institutions accept CIRB reviews, but NCI plans to expand it to 100 sites over the next few months.

"It's still a tricky issue," Abrams said. "Many hospitals are reluctant to give up local control."

However, many IRBS are overworked and may have little oncology expertise. "With the CIRB, sites will get a high-quality review, and more time to focus on local, single-institution studies," Abrams said. "This should allow investigators to get trials going more quickly and may allow investigators to offer more trials to patients."

Local IRBs can rarely influence the conduct of a large, national study, Abrams said. "Local IRBS are in an all-or-nothing position," he said. "The Central IRB does have the power to speak to the study investigators and change things. It's a much more powerful IRB."

An article on the CIRB, written by NCI officials, was published in the May 2 issue of the New England Journal of Medicine.

NCI has hired a contractor to review the CIRB process, to evaluate the quality of the review, identify factors affecting local acceptance of CIRB review, and conduct surveys of investigators, CIRB members, and cooperative groups.

Also, NCI is developing a unified database of physicians for IRB reviews. Previously, oncologists involved in trials had to register with each cooperative group. The database is scheduled to become available in October, Abrams said.

**Concept Evaluation Panels**

NCI plans to evaluate its Concept Evaluation Panels, another initiative designed to provide speedier review of proposed phase III trials prior to acceptance by the CTSU.

Since it began in October 1999, the CEPs have reviewed 40 phase III concepts for lung and GU studies, approved 15, recommended revision and resubmission for 11, and disapproved 14.

In the 56 months prior the CEPs, 35 lung and GU concepts were reviewed and 21 approved.

"We're getting more concepts, but approving a lower percentage overall," Abrams said in a presentation earlier this year to the National Cancer

Advisory Board. "We haven't slowed the process down."

As a result of an evaluation by panel members, the scoring system has been simplified.

After NCI's evaluation in the next six months, a decision will be made whether to expand the panels to other cancers, Abrams said.

Further information on the NCI clinical trials initiatives may be found at the following Web sites:

Clinical Trials Support Unit: http://www.ctsu.org/

Overview of NCI pilot projects: http://cancertrials.nci.nih.gov/system.

*Professional Societies:*

## AACR Supports Full Funding Of NCI Bypass Budget

The American Association for Cancer Research said it strongly supports full funding of the NCI Director's Bypass Budget request for 2003.

The $5.69 billion request represents NCI's best judgment of the level of funding necessary to fund ongoing needs and capitalize on unprecedented opportunities to accelerate progress against cancer.

The NCI Bypass Budget is $1.5 billion more than the FY2002 President's Budget. The AACR also supports completing the five-year doubling of the budget of NIH in 2003 and funding key programs at the Center for Disease Control that are focused on early detection and prevention of cancer and cancer control.

"This is a pivotal period in cancer research. The sequencing of the human genome and breakthrough discoveries across all of biomedical research have created a stunning array of options to make real strides toward our goal of preventing and curing cancer for all Americans," said Margaret Foti, chief executive officer of AACR. "Fully funding the NCI Director's Bypass Budget is one sure way to leverage our progress in research into more effective drugs, technologies, and strategies to prevent and treat cancer."

The return on the increased investments in research through the NCI Bypass Budget will provide funds needed to building the nation's research infrastructure, support more new meritorious research ideas, and train the future research and healthcare workforce, AACR said.

Although fully funding the 2003 Bypass Budget will facilitate achieving a number of critical objectives, the following represents examples of expected advances in critical areas, AACR said:

—Increase the percentage of approved investigator-initiated research grants from 25 percent to 35 percent, as these grants drive advances in cancer and biomedical research.

—Double the number of cancer patients entering state-of-the-art clinical trials and expand quality-of-care research.

—Strengthen the cancer surveillance system to quickly identify emerging trends in cancer incidence and mortality and provide new resources to investigate cancer disparities.

—Provide essential career development support for physicians in cancer research.

—Expand research investment in six high priority areas (genes and the environment; cancer imaging; cancer cell signatures: detection, diagnosis, and therapy; molecular targets of prevention and treatment; research on tobacco and tobacco-related cancers; and cancer communications).

"We applaud President Bush's leadership, his bold stand in the war on cancer, and especially his commitment to complete the doubling of the NIH by proposing a funding level of $ 27.3 billion for the NIH in 2003," said Waun Ki Hong, of the M. D. Anderson Cancer Center, and past president of AACR. "This will certainly provide some of the support for biomedical and cancer research needed to ultimately prevent and cure cancer."

The President's Budget for 2003 suggests that funding increases for NIH may fall to the 2-3 percent level after 2003, which would significantly slow progress in cancer research progress, AACR said.

AACR recommended that when the doubling of the NIH budget is completed next year, Congress should fund NIH and NCI at a minimum increase of 10 percent per year.

*NIH News:*

## Publicly-Funded Consortium Sequences Mouse Genome

The international Mouse Genome Sequencing Consortium said it has assembled and deposited into public databases an advanced draft sequence of the mouse genome

This achievement represents a milestone for the Human Genome Project because it provides a key tool needed to interpret the human sequence, a draft version of which was published last year, NIH officials said.

This information will allow researchers to gain insights into the function of many human genes because the mouse carries virtually the same set of genes as the human but can be used in laboratory research.

"The mouse sequence is much further along in the process than the human sequence was at the draft stage," said Francis Collins, director of the National Human Genome Research Institute. "Methods for efficient sequencing of large genomes continue to advance dramatically, and the sophistication of the team that accomplished this goal is truly impressive. This sets a new standard for speed, accuracy, and public accessibility."

Having this draft of the mouse sequence will greatly accelerate precise identification of the genetic contributors to illnesses, leading to better understanding of human disease and improved tests and treatments, NHGRI said. The mouse sequence will also allow researchers to recognize functionally important regulatory elements in the human genome by virtue of the fact that they are conserved through the 100 million years of evolution separating humans and mice.

"The mouse sequence provides a very important chapter from evolution's lab notebook," said Eric Lander, director of the Whitehead/MIT Center for Genome Research. "Being able to read evolution's notebook and compare genomic information across species will allow us to glean important information about ourselves. That's because evolution preserves the most important genetic information across species; if specific DNA sequences have been preserved by evolution over hundreds of millions of years, then they must be functionally important."

The draft sequence was assembled by the Mouse Genome Sequencing Consortium, an international team of researchers from the Whitehead Institute in Cambridge, MA, Washington University School of Medicine in St. Louis, MO, and the Wellcome Trust Sanger Institute and the European Bioinformatics Institute, in Hinxton, England, with funding from NIH and the Wellcome Trust in the United Kingdom.

The draft sequence shows the order of the DNA chemical bases A, T, C, and G along the mouse chromosomes. The current assembly includes more than 96 percent of the mouse genome with long, continuous stretches of DNA and represents a seven-fold coverage of the genome. This means that the location of every base, or DNA letter, in the mouse genome was determined an average of seven times, a frequency that ensures a high degree of accuracy.

"It is remarkable that we were able to complete the mouse genome in such a short time and with such great accuracy," said Robert Waterston, director of the Genome Center at Washington University. "We are now working hard with an international group of experts to explore the content of the sequence and to use it to improve our understanding of the human sequence."

The mouse genome is contained in 20 chromosome pairs and the current results suggest that it is about 2.7 billion base pairs in size, or about 15 percent smaller than the human genome. The human genome is 3.1 billion base pairs spread out over 23 pairs of chromosomes (22 autosomes and the X and the Y sex chromosomes).

Analysis of the genome assembly indicates roughly the same number of genes for the mouse as the human. So far researchers have found more than 22,500 high-quality gene predictions, with additional predictions expected to take the total to about 30,000.

The quality of the working draft sequence far exceeds the consortium's original expectations for this stage and was completed much sooner than initially expected, reflecting the tremendous efficiencies gained in sequencing and computational technologies in the past few years.

Officials said the mouse sequencing strategy combines the best features of the clone-based, hierarchical-shotgun and whole-genome-shotgun strategies. The scientists used data from more than 33 million individual sequencing experiments. Using two different computer systems, called genome assemblers, the team reconstructed the 33 million individual fragments into a draft sequence. These whole-genome assemblers, called ARACHNE and PHUSION were developed at the Whitehead Institute and at the Sanger Institute.

These long stretches of sequence, called contigs, were then linked into larger fragments called supercontigs of a typical length of 16.9 million base pairs. These supercontigs were then anchored to the mouse genetic and BAC clone maps. Finally, adjacent supercontigs were joined into even larger ultracontigs on the basis of other linking information. In the end, nearly the entire chromosomal sequence is contained in a mere 89 ultracontigs with a typical size of 50 megabases each.

"The mouse genome project has stimulated the development of two excellent computer algorithms

for assembling very large genomes in the public domain," says Jane Rogers, at the Sanger Institute. "This will be enormously valuable for analyzing further genomes."

The sequence information can be found at several Web sites, including http://mouse.ensembl.org at the European Bioinformatics Institute; at http://www.ncbi.nlm.nih.gov/genome/guide/mouse at the National Center for Biotechnology Information at the National Library of Medicine, and http://genome.ucsc.edu at the University of California, Santa Cruz.

The consortium plans to produce a "finished" version with the remaining gaps (the 4 percent where the sequence has yet to be determined) filled in and errors resolved. This phase will proceed using clone-based, or hierarchical, sequencing using the publicly available mouse genome clone map. A mapped set of BAC clones that covers the entire mouse genome is being sequenced. The BAC data will be combined with the draft genome sequence to finish the mouse sequence to the same high quality to which the human sequence is being completed. Clone-based sequencing remains the only method proven to produce a complete, fully accurate version of a complex genome, NIH officials said.

The complete genome sequence of the mouse is expected to be available within 3 years.

* * *

**National Institute of Allergy and Infectious Diseases** has renewed and expanded its contract for a facility at Emory University that provides tetramers, a new technology in T-cell research, useful for research in vaccines, cancer, and biodefense.

Tetramers are complexes of four identical copies of the key proteins that can stimulate specific T cells. In cancer research, tetramers can determine which components of a tumor cell trigger the body's defenses, NIAID said. Under the terms of the contract, tetramer facility scientists will provide so-called class I and class II tetramers. To date, the facility has provided only class I tetramers. Class II tetramers, which will be available soon, identify the helper T cells that promote antibody production and help coordinate immune responses to infection and vaccination.

The renewed five-year contract, at an estimated $980,000 per year, will be funded by NIAID with support from NCI. The facility is directed by Emory's John Altman. For further Information, see http://www.niaid.nih.gov/reposit/tetramer/index.html.

*Funding Opportunities:*

# RFA Available

**RFA-DK-02-032: George M. O'Brien Urology Research Centers**

Letter of Intent Receipt Date: Oct. 17, 2002

Application Receipt Date: Nov. 19, 2002

The emphases for the program are fourfold 1. to continue to attract new scientific expertise into the study of the basic mechanisms of urological diseases and disorders; 2. to encourage multidisciplinary research focused on the causes of these diseases; 3. to explore new basic areas that may have clinical research application; and 4. generate developmental research/pilot and feasibility studies of two years duration, which would lead to new and innovative approaches to study urological disease, and the eventual submission of competitive investigator-initiated R01 research grant applications. The RFA will use the NIH P50 specialized center award mechanism.

The RFA is available at http://grants1.nih.gov/grants/guide/rfa-files/RFA-DK-02-032.html.

Inquiries: Leroy Nyberg, Jr., director, Urology Programs, Division of Kidney, Urology, and Hematology, National Institute of Diabetes and Digestive and Kidney Diseases, NIH, 6707 Democracy Blvd, Rm 627, Bethesda, MD 20892-5458, phone 301-594-7717; fax 301-480-3510; e-mail ln10f@nih.gov

# Program Announcements

**PA-02-100: Complex formation in Hormonal Regulation of Gene Expression**

NIH centers and institutes invite applications for specific research objectives which include: 1. Role of coactivators/corepressors in the regulation of tissue-specific gene expression 2. Role of cytoplasmic factors in hormone or receptor processing and/or signal propagation to the nucleus 3. Identification of model systems that allow for study in vitro or in vivo of gene expression 4. Role(s) of nuclear accessory proteins in regulation of nuclear hormone action in target cells 5. Novel factor(s) associated with hormone action involved in disease genesis, including breast and prostate cancer, obesity, insulin resistance, diabetes, and osteoporosis 6. Selective Receptor Modulators with potential effects on disease development and/or progression 7. Structural biology of receptor/interacting protein and/or cofactor

interaction focusing on interactions with other receptor interacting proteins, co-activators or co-repressors, the ligand, or HREs in signal propagation 8. Role(s) of chaperone proteins in regulating receptor function and/or interaction with ligands or nuclear accessory proteins, including nuclear localization and/or proteasomal degradation 9. Signaling cross-talk between classes of receptors and cytoplasmic and/or nuclear accessory proteins and effects on regulation of gene expression and disease initiation/progression 10. Molecular mechanisms by which Breast and Prostate tumors acquire hormone-independence. The PA will use the NIH R01 and R21 award mechanisms.

The PA is available at http://grants.nih.gov/grants/guide/pa-files/PA-02-100.html.

Inquiries: Neeraja Sathyamoorthy, program director, Tumor Biology & Metastasis Branch, Division of Cancer Biology, NCI, 6130 Executive Blvd EPN 5036, Rockville MD 20892, phone 301-435-1878; fax 301-480-0864; e-mail ns61r@nih.gov

**PA-02-103: Research on Ethical Issues in Human Studies**

NIH institutes and centers invite research grant applications (R01) to investigate ethical issues in human subjects research. The research would address the ethical challenges of involving human participants in research and to inform and optimize protections for their participation.

In pursuing NIH-funded human research, investigators, institutions, and IRB members must adhere to several general ethical principles, including: Respect for Persons—individuals should be treated as autonomous agents and persons with diminished autonomy are entitled to additional protections; Beneficence—efforts must be made to maximize possible benefits and minimize possible harms; and Justice—individuals or groups of individuals should not be unduly burdened as a result of participating in research and individuals or groups of individuals should not disproportionately benefit as a result of participating in research (http://ohrp.osophs.dhhs.gov/humansubjects/guidance/belmont.htm). The PA will use the NIH R01 award mechanism. The PA is available at http://grants1.nih.gov/grants/guide/pa-files/PA-02-103.html.

Inquiries: For NCI—Mary McCabe, Bldg. 31 Rm 3A-44, Bethesda, MD 20892, phone 301-496-6404; fax 301-496-0826; e-mail mccabem@mail.nih.gov

## Other Funding Notices

**NOT-GM-02-003: NIGMS Participation in Innovative Toxicology Models: SBIR/STTR PA-02-075**

NIGMS has an established interest in understanding interactions of therapeutic drugs or their toxic metabolites with cellular components that may result in the development of toxic effects. The original PA is available at (http://grants.nih.gov/grants/guide/pa-files/PA-02-075.html).

The notice is available at http://grants1.nih.gov/grants/guide/notice-files/NOT-GM-02-003.html.

Inquiries: Richard Okita, Pharmacology, Physiology & Biological Chemistry Division, NIGMS, 45 Center Dr., Rm 2AS-49A, Bethesda, MD, 20892-6200, phone 301-594-1826; fax 301-480-2802; e-mail okitar@nigms.nih.gov

**NOT-OD-02-048: Last NIH Regional Seminar in Program Funding and Grants Administration for 2002**

NIH holds two seminars a year that are designed to help research faculty and administrators learn the fundamentals of preparing a strong application and navigating the review process, better understand the roles and responsibilities of parties involved in Federally funded research, and clarify Federal regulations and policies. The seminar, appropriate for grants administrators, new researchers and graduate students, will be hosted by the University of Louisville on June 6-7 in Louisville.

The full seminar program and registration information is available at http://grants.nih.gov/grants/seminars.htm.

*In Brief:*

## Joann Schellenbach To Retire From American Cancer Society

(Continued from page 1)

late August or early September. . . . **JOANN SCHELLENBACH**, the American Cancer Society national director for medical and scientific communications, will retire after 22 years on the society's staff. Through most of her career, Schellenbach ran media relations, organized a popular annual seminar for science writers, and served as a contact for patient advocacy groups. Schellenbach said she plans to write about science and consult on

press relations. Her personal email address is jschellenbach@nyc.rr.com. . . . **JOSEPH FRAUMENI,** director of the NCI Division of Cancer Epidemiology and Genetics, was elected to membership of the Institute of Medicine of the National Academy of Sciences. He began his career at NCI in 1962 as a staff associate and was appointed director of the DCEG in 1995. Fraumeni serves as adjunct professor of epidemiology at the Harvard School of Public Health and the Uniformed Services University of the Health Sciences. . . . **VANITY FAIR**, in its June issue, published a lengthy piece about the troubled biotech company ImClone Systems Inc. and its brothers-executives **Samuel** and **Harlan Waksal**. Reporter **Alex Prud'homme** dug deep into the Waksals' past, ferreting out colorful stories from the history of ImClone and the Waksals' turbulent youth, and describing the recent debacle over the development of ImClone's cancer drug C225. . . . **T. DOUGLAS LAWSON** was appointed president of The Cancer Institute, of Kansas City, Mo., effective May 1. He was interim president as well as system vice-president in the Saint Luke's Shawnee Mission Health System. Prior to joining St. Luke's, Lawson was vice president and chief operating officer for the M.D. Anderson Cancer Network. . . . **JEROME HAUER,** advisor for national security and emergency management, has been appointed director of the Office of Public Health Preparedness by HHS Secretary **Tommy Thompson**. He will oversee and coordinate the planning, response and recovery efforts for all emergencies, including acts of terrorism. Hauer is known for developing the first bioterrorism response plans while director of Emergency Management for New York City. He is replacing **D.A. Henderson**, who will continue as principal science advisor to the Secretary for public health preparedness and as chairman of the Secretary's Council on Public Health Preparedness. . . . **FRED SCHUSTER,** regional director and acting state administrator for Sen. **Charles Grassley** (R-IO), was named HHS regional representative for region IV, based in Kansas City, MO. The area includes the states of Iowa, Kansas, Missouri and Nebraska. The appointment completes the placement of representatives in all 10 U.S. regions by HHS Secretary Thompson.

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