# THE CANCER LETTER

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# NIH Director's Office Funds \$106 Million In Cancer Grants With Stimulus Dollars

By Kirsten Boyd Goldberg

Cancer researchers and institutions have captured \$106 million in federal economic stimulus funding from the NIH Office of the Director so far in the first eight months of the 18-month time period for receiving the additional dollars, NCI Director John Niederhuber said earlier this week.

Under the American Recovery and Reinvestment Act passed by Congress and signed by President Obama last February, NIH received \$10.4 billion, of which \$7.4 billion went to its 27 institutes and centers (The Cancer Letter, Feb. 20). The remaining funds, minus \$500 million for internal NIH facilities (Continued to page 2)

#### Capitol Hill:

# **Senate Appropriators Reject President's \$228 Million Increase For Cancer Research**

By Paul Goldberg

The Senate Appropriations Committee rejected the Obama administration's proposal for an increase of \$228 million for cancer research, noting that funding levels for diseases should be determined without political interference.

The Senate bill gives NIH \$30.8 billion for fiscal 2010, a \$442 million (1.45%) increase over the current year, including \$5.05 billion for NCI.

The House appropriations bill gives NIH \$31.259 billion, an increase of \$942 million (3.1%) over the current year. The proposed NCI appropriation is \$5.15 billion, a \$181 million (3.6%) boost.

Both Congressional numbers for NIH are above the administration request, which gives \$30.759 billion for NIH for fiscal year 2010, an increase of \$443 million (1.5%) over the current year. NCI would get \$5.15 billion under the President's budget request.

The House bill was passed by the full House on July 24, but the full Senate is yet to act on the bill passed by Senate appropriators July 30. The text of the House report follows:

**National Institutes of Health**—Fiscal year 2009 has been a year of unprecedented opportunity for NIH. The combination of Recovery Act funding and the fiscal year 2009 Omnibus Appropriations Act increased the NIH appropriation by almost 40 percent.

NIH is required to spend all Recovery Act funding in two years in order to spur economic recovery. NIH has risen to that challenge and has created new types of grants that aim to produce defined results in a two-year period, (Continued to page 3)

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# **Challenge Grant Success Rate** 20 Percent Overall, NCI Says

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upgrades, are available under several competitive grant programs. As of Sept. 11, cancer researchers had won the following in NIH funding:

- —27 comparative effectiveness research grants for \$61 million.
- —77 awards for summer student programs for \$4.5 million.
- —18 Grand Opportunities grants for \$23.8 million.
  - —18 Challenge Grants for \$17.7 million.

For the Challenge grants and Grand Opportunities grants, NCI divisions and centers put forward cancer research ideas for investigators to respond to. Chalenge grants were reveiwed by NIH and scores were brought back to NCI.

"We looked at them and selected 10 percent that had been scored and sent them to NIH as our wish list," Niederhuber said. NIH funded 18 of the 37 grants NCI had selected for NIH funding. Also, NIH funded 15 NCI Challenge grants in comparative effectiveness research for \$13.2 million.

NCI then selected an additional 41 "high-priority" grants and used it's funding to support these for \$38 million.

"Pending the availability of ARRA funds, NCI may select additional grants" to fund later, Niederhuber said.



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The overall Challenge grant success rate was 20 percent of grants reviewed and scored.

The GO grants were reviewed within NCI, but NIH selected 18 of those for co-funding. NCI funded 33 additional GO grants for \$64 million, in the areas of AIDS (21 awards for \$21 million); functional biology (five awards for \$24 million); translational research (five awards for \$16 million); and viruses and cancer (two awards for \$3 million).

Also, NIH fully funded 12 NCI GO grants in comparative effectiveness research for \$48 million.

The overall success rate for GO grants was 17 percent of grants reviewed.

#### With ARRA Funds, Payline Up to 25th Percentile

Nearly 60 percent of the federal economic stimulus funding provided to NCI will be used to support extramural grants, while 39 percent will fund research and development contracts, Niederhuber said.

NCI received \$1.256 billion from the recovery act. The funding must be spent by Sept. 30, 2010.

Niederhuber provided the most detailed description to date of the institute's plans for the funding, in a budget update to the National Cancer Advisory Board on Sept. 15.

At the end of fiscal 2008, the institute's research project grant payline was at the 12th percentile, having suffered from a flat budget since 2004, Niederhuber said.

This year, in addition to the stimulus funds, NCI received a 2.9 percent increase in Congressional appropriations, for an budget of \$4.968 billion.

With the increase in appropriations, NCI was able to raise its grant payline to the 16th percentile. The institute expects to fund 7,075 grants by the end of the fiscal year Sept. 30.

By adding in ARRA funds, the institute extended the payline to the 25th percentile to support a mix of two-year and four-year grants using stimulus funds for the first two years and committing future appropriations for the following two years. Stimulus funds are also being used to fund grants for new investigators. As of Sept. 11, NCI had funded 369 grants using stimulus dollars.

NCI's financial managers "carefully modeled" the funding plan to ensure that the institute will be able to support the additional grants when the stimulus funding ends, Niederhuber said. The regular budget and the stimulus funds must be accounted for separately. The stimulus funding also comes with extra reporting requirements for the institute and the entities that receive the funds.

Of the institute's stimulus funding, 59 percent, or \$731 million, will be spent on grants; 39 percent, or \$493.8 million, will fund R&D contracts for the academic community; \$6.3 million will pay for equipment for the NCI intramural program; and 2 percent, or \$25 million, was set aside for support services. NIH tapped about \$10 million of the support services funding. NCI is using those dollars to pay travel costs for scientists coming to NIH to review the ARRA grants.

"No dollars went into the research component of the intramural program," Niederhuber said.

NCI will use about \$342 million of stimulus funding for grant and administrative supplements, such as faculty start-up grants at cancer centers to help centers with recruitment. The success rates for the supplements were 16.6 percent for equipment, and 15 percent for general support.

The payline for competitive supplements was 23 (based on priority score).

In the area of contracts, NCI will use the stimulus funds to support cohort studies, phase I and II therapeutic and imaging trials, expansion of the Chemical Biology Consortium and the therapeutics program, caBIG's Cancer Cloud program, the Division of Cancer Treatment and Diagnosis clinical assay development and molecular characterization centers, The Cancer Genome Atlas, and NCI's Therapeutically Applicable Research to Generate Effective Treatments (TARGET) Initiative to identify valid therapeutic targets in childhood cancers.

Also, the institute plans to use stimulus funds to support 37 early phase clinical trials of new treatment regiments, under a program called Accelerating Clinical Trials of Novel Oncologic Pathways. The awards are contingent on IRB approval and opening the trial to patient enrollment within 90 days and completion in two years.

Niederhuber provided the following list of NCI's ARRA funding by organ site:

- —Breast cancer: 76 grants, \$14.7 million.
- —Prostate cancer: 54 grants, \$7.4 million.
- —Colorectal cancer: 40 grants, \$7.2 million.
- —Lung cancer: 35 grants, \$6 million.
- —Pancreatic cancer: 17 grants, \$2.9 million.
- —Ovarian cancer: 8 grants, \$1.4 million.

Awards under the ARRA program take longer to reach grantees, because the funding decisions must be approved by NIH, the Office of Management and Budget, and the Vice President's office, Niederhuber said.

"What are people doing at these various levels?" asked NCAB member Bruce Chabner, clinical director

of the Massachusetts General Hospital Cancer Center.

"This is a unique process for the ARRA funds," Niederhuber said. "It comes from the administration's concern that this amount of money put into a stimulus package should be carefully monitored. I'm not being critical, I'm just saying it made it difficult to be timely."

At one point, the word came back to NIH that some grant titles needed to be changed, because they might be "misinterpreted by the press or the public," Niederhuber said. None were NCI grants. "After a while they sort of just threw up their hands and said go ahead and get these grants out."

#### **ASCO: More NCI Support For Clinical Trials**

Douglas Blayney, president of the American Society of Clinical Oncology, urged the National Cancer Advisory Board to encourage NCI to increase per-case reimbursement for NCI-funded clinical trials.

Inadequate support for investigators, staff, and infrastructure harms the clinical trials system, which is also struggling to improve its operational efficiency, Blayney said. NCI needs to give its cooperative groups more flexibility to support investigators, he said.

# Capitol Hill:

# **Both Houses Reject Specific Funding Level For Cancer**

(Continued from page 1)

along with expanding current grants to pursue new inquiries. NIH is on track to obligate all Recovery Act funding by the end of fiscal year 2010.

The committee is convinced that investing now in NIH research will generate untold breakthroughs that will improve health and reduce health care expenditures in the future. The nation's return on investment in NIH includes declines in death rates for cardiovascular diseases and an increase in cancer survivorship, as just two examples.

NIH is the largest single engine for biomedical research in the world. The pace of discovery in the biomedical sciences has never been as rapid or as promising. NIH funding supports more than 300,000 scientists and research personnel affiliated with more than 3,100 organizations in all 50 States.

The committee is concerned by the harmful precedent established in the Administration's budget of setting specific funding levels for particular diseases. The committee believes it is more appropriate to allocate funding in a way that permits scientific peer review to

decide the most promising research to support. The serendipitous nature of science is documented each year, with breakthroughs in one disease area emanating from a finding in a completely unrelated field.

The committee recognizes these unanticipated opportunities by recommending a funding level which provides a comparable inflationary adjustment to the fiscal year 2009 levels for each institute and center to offset biomedical research inflation; includes resources to finance 10,739 new and competing grants, an increase of 914 over fiscal year 2009 (excluding the grants supported with Recovery Act funding); and provides an average two percent increase for both new and continuing grants to maintain the grants' purchasing power.

The number of total grants will rise to 38,888, an increase of 1,105 over fiscal year 2009. The recommendation is attentive to the pipeline issue, providing funding for two programs to support young investigators as well as a two percent average increase in research training stipends. The committee fully funds the Administration's request of \$300,000,000 for transfer to the Global Fund for AIDS, Malaria and Tuberculosis and continues the National Children's Study with an appropriation of \$194,400,000. The Common Fund is supported as a set-aside within the Office of the Director at \$534,066,000.

**National Cancer Institute**—The committee continues bill language identifying up to \$8,000,000 for repairs and improvements at the NCI-Frederick Federally Funded Research and Development Center in Frederick, Md.

Adult Acute Leukemia—The committee is encouraged by ongoing research on adult acute leukemia, particularly in understanding how changes in a person's DNA can cause bone marrow cells to develop into leukemia, the detection of minimal residual disease which can indicate a relapse in the disease, and the discovery of more effective chemotherapy drugs. The committee encourages NCI to expand current studies and support promising new research through all available mechanisms.

Blood Cancers—The committee is aware that there are currently over 800,000 blood cancer patients living in the United States, and that the incidence of certain blood cancers has increased in recent decades. Public Law 107-172 directed NIH to expand, intensify, and coordinate programs for the conduct and support of research with respect to blood cancer, and particularly with respect to leukemia, lymphoma, and multiple myeloma. These diseases constitute one of the leading

causes of cancer deaths. In addition, the committee urges NCI to increase its focus on more rare forms of blood cancer such as Waldenstrom's macroglobulinemia.

CIS Partnership Program—The committee is concerned about NCI's decision to eliminate the Cancer Information Service Partnership program, which has provided high quality, accurate information to more than 10 million Americans at a vulnerable time in their lives.

The Congressional mandate for this program states "to provide and contract for a program to disseminate and interpret, on a current basis, for practitioners and other health professionals, scientists and the general public, scientific and other information respecting the cause, prevention, diagnosis and treatment of cancer."

The CIS Partnership program supports over 750 partners who work with a diverse population who make use of its cancer information and communications research laboratory. The committee recommends that NCI keep the present CIS Partnership office in place until 2011 and requests that NCI conduct an evaluation of the program, develop a detailed plan on how it intends to fulfill the Congressional mandate for CIS, and report its findings to the Committees on Appropriations of the House of Representatives and the Senate no later than February 1, 2010.

Gastrointestinal Cancer—The committee is concerned that early diagnosis of most GI cancers is difficult or impossible, especially aggressive GI cancers in young people, and curative treatment options are non-existent at later stages. The committee encourages NCI to study GI cancers in people age 40 and under, giving emphasis particularly to late-stage cancers for whom curative treatment options are unavailable. In addition, the committee requests NCI to consider developing an interconnected gastrointestinal cancer biorepository with consistent, interoperable systems for collection, storage, annotation, and information sharing.

Gynecologic Cancer SPOREs—The committee is encouraged by the success of the gynecological cancer SPORE program. At present there is no available screening test for ovarian cancer to identify the disease at an early stage and improve survival. Given the inadequacies of current tools, there is a pressing need for new effective screening technologies, as well as for the development of new targeted therapies to decrease the mortality and morbidity of this disease. In addition, there is a need for research that is focused on endometrial and uterine cancer. The committee encourages NCI to support existing gynecologic cancer SPORES as well as to consider increasing their overall number.

Gynecologic Oncology Clinical Trials—The committee is concerned that the gynecology clinical trials network has not been able to fully fund an institution's research costs when it enrolls patients in a trial. This may have the impact of limiting access for patients to these trials which are offering cutting edge cancer treatments. This may also negatively impact the pace with which these clinical trials can be completed and results evaluated and published. The committee encourages NCI to reconsider the per patient research costs of these clinical trials.

Hematology—The committee is aware of efforts being made by the Institute's Office of Latin American Cancer Program Development to train physicians and scientists in the development of clinical trials and collaborative research networks focused on blood cancers. The committee encourages NCI to support these international programs, which will improve research mechanisms and access to novel treatments for cancer patients.

HPV Vaccine and Cervical Cancer—The committee encourages NCI to study clinical and cost analysis benefits of prospectively tracking cytologic screening and HPV test results and outcomes in communities where HPV vaccines are being implemented. The committee encourages NCI to fund research, including registry-based tools, that will permit identification of the most cost-effective management strategy for cervical cancer screening in the era of HPV vaccines and will identify the circumstances where current screening protocols fail.

Liver Cancer—The committee urges NCI to focus research efforts on liver cancer, which continues to be one of the fastest growing cancers in the U.S. The committee encourages NCI to pursue new interventions and treatments, as well as new methods for early detection and prognosis.

Lung Cancer—The committee remains concerned about increased lung cancer rates among women and urges NCI to support research for lung cancer diagnosis and treatment.

Melanoma—The committee is encouraged by the collaboration between NCI and the advocacy and research community on prioritizing NIH-funded melanoma research that resulted in a community-oriented strategic action plan for melanoma research. The committee encourages NCI to support the areas of research identified by the strategic research plan. Furthermore, the committee encourages NCI to include melanoma in the Cancer Genome Atlas consortium to help identify new markers for classification,

detection and risk-assessment, particularly in high-risk populations.

Mitochondrial DNA and Cancer—The committee is aware that mitochondrial DNA mutations are associated with numerous cancers and that NCI has increased its efforts to better understand this relationship. The committee encourages the Institute to continue its involvement in this area of research.

National Disparities—NCI has developed and supported a national network of designated cancer centers at academic medical centers across the nation as a premier vehicle for promoting cancer research and outreach. These centers are particularly valued in their regions and States for their role in supporting all facets of cancer research, prevention, control and education. The committee notes the incidence of national disparities in cancer prevalence, diagnosis, treatment, and control, particularly within regions with large underserved and minority populations with poor access to these centers.

In order to reach these populations and extend the benefits of designated cancer centers, the committee recommends that NCI consider supporting developing centers through the renewal of the NCI planning grant program. This grant mechanism will support the development of additional designated cancer centers that will bring the benefits of cancer research, prevention, control, and outreach fostered at these centers to those populations most in need.

Neuroblastoma—The committee continues to encourage NCI to accelerate support for neuroblastoma research, with a focus on clinical trials for high-risk patients. Given the poor survival rates for children with advanced disease, the committee encourages NCI to prioritize support for all promising neuroblastoma research, both intramural and extramural.

Pancreatic Cancer—While there has been a continuing decline in mortality rates for many types of cancer, mortality rates for pancreatic cancer have changed little in the past 30 years. Further, survival rates have changed little in the last 30 years. The committee last year urged NCI to launch a pancreatic cancer-specific research and training initiative. To further these efforts, the committee encourages NCI to convene a conference of internal program and research staff to jointly assess the current status of the pancreatic cancer research and training initiative and to develop an action plan for the use of fiscal year 2010 funding. The committee requests a report on the results of that meeting within 60 days of its occurrence.

Pediatric Cancer—The committee urges NCI to

intensify pediatric cancer research, including laboratory research, to identify and evaluate potential therapies, preclinical testing, and clinical trials through cooperative clinical trials groups. This research should include research on the causes, prevention, diagnosis, treatment, and late effects of pediatric cancer.

The committee also requests that NCI report to the Committees on Appropriations of the House of Representatives and the Senate by June 1, 2010 on the actions it has taken to implement the research-specific portions of the Caroline Pryce Walker Conquer Childhood Cancer Act.

Reproductive Scientists Development Program— The committee urges NCI to continue its partnership with NICHD with regard to training the next generation of gynecologic cancer researchers. The success of the Reproductive Scientists Development Program Fellows is reflected in the fact that a majority of these individuals receive an investigator-initiated grant and continue to prosper as a career-clinician scientist.

Separately, the House report contains a mandate for Centers for Disease Control and Prevention to launch a breast cancer education program aimed at young women. The langiage coincides with a controversial bill by Rep. Debbie Wasserman-Schultz (D-Fla.):

Breast Cancer Awareness for Young Women— Breast cancer is the most commonly diagnosed cancer among women. There are approximately 180,000 new cases and 40,000 deaths from breast cancer annually. According to data from U.S. Cancer Statistics Report from 2001-2005, approximately five percent of all female invasive breast cancers are among women under 40 years of age. Raising awareness among providers and the public about the importance of early detection can result in improved outcomes and quality of life for cancer survivors. Within the total for breast and cervical cancer, the committee includes \$5,000,000 for breast cancer awareness for young women. The committee encourages CDC, in collaboration with HHS, the National Cancer Institute, and the Agency for Healthcare Research and Quality to develop evidence-based initiatives to advance understanding and awareness of breast health and breast cancer among women at high risk for developing breast cancer, including women under 40.

Senate Report on NIH—The committee understands that the recommended fiscal year 2010 funding level falls below the amount needed to keep up with biomedical inflation, and that the NIH could face severe financial pressures in fiscal year 2011. But the committee notes that the record-high increase

for the NIH in the ARRA greatly mitigates the need for more funding than the administration requested in fiscal year 2010. While additional funding for the NIH could help ease the budgetary pressures in fiscal year 2011, that alone is not a sufficient reason to go beyond the administration's budget request in fiscal year 2010, especially when many other important programs in this bill that did not receive increases in the ARRA face immediate pressures of their own.

The committee rejects the administration's proposals to earmark an increase of \$268,000,000 for research on cancer and an increase of \$19,000,000 for research on autism. The devastating effects of cancer and autism are well known, and additional federally supported research in these areas is certainly warranted. However, the President's plan would set a dangerous precedent. The committee has long subscribed to the view that funding levels for individual diseases should be determined without political interference. If Congress were to earmark funds for cancer and autism, advocates for a multitude of other health problems would justifiably demand similar treatment. In the long run, no one's interest would be served if Members of Congress with no professional expertise in medical research were asked to make funding decisions about hundreds of diseases and health conditions.

The committee also notes that the proposed increases for cancer and autism research total \$287,000,000 of the \$441,764,000 overall proposed increase for NIH. It is hard to justify to those whose lives have been touched by heart disease, diabetes, COPD, Alzheimer's disease and stroke, to name a few other high-morbidity diseases, that research in just two areas deserves almost two-thirds of all the new funding in fiscal year 2010.

The committee recommends \$549,066,000 for the Common Fund, the same amount as the budget request. The fiscal year 2009 level was \$541,133,000.

Senate Report on NCI—In general, the committee urges the Institute to put a high priority on developing early detection tools and treatments for those cancers that remain most lethal; supporting behavioral, health services, and other research geared to better apply what is known about cancer prevention and early detection; addressing cancer-related health disparities; and promoting pain and symptom management, as well as other palliative and psychosocial care research aimed at improving quality of life for cancer patients, survivors, and their caregivers.

Asian/Pacific Islanders—The committee notes

that Asian and Pacific Islanders have a high incidence of stomach and liver cancers compared to Caucasians, and it urges the NCI to focus on the special needs of this population.

Cancer Metabolism—The committee encourages the NCI to support more research on cancer metabolism, specifically how cancer cells become addicted to using more nutrients than normal cells to ensure their survival and growth. Research targeting these metabolic pathways could have a profound and broad effect on cancer cell survival and tumor growth, and ultimately cancer treatment.

Gastrointestinal Cancer—The committee encourages the NCI to put a higher priority on GI cancers in people age 40 and under, giving emphasis particularly to late-stage cancers for which curative treatment options are unavailable. In addition, the committee requests the NCI to consider developing an interconnected gastrointestinal cancer biorepository with consistent, interoperable systems for collection, storage, annotation, and information sharing.

Hematology—The committee is aware of efforts being made by the Institute's Office of Latin American Cancer Program Development, in conjunction with the American Society of Hematology, to train physicians and scientists in the development of clinical trials and collaborative research networks focused on blood cancers. The committee encourages international programs such as this, which will improve research mechanisms and access to novel treatments for cancer patients.

Human Papillomavirus Vaccine and Cervical Cancer—The committee urges the NCI to fund research, including registry-based tools, that will allow for the identification of the most cost-effective management strategies for cervical cancer screening in communities where HPV vaccines are being implemented and to identify the circumstances where current screening protocols fail.

Liver Cancer—The committee supports a stronger focus on liver cancer, which continues to be one of the fastest growing cancers in the Nation during a time when the overall incidence of cancer has stabilized. The committee urges that new interventions and treatments, as well as new methods for early detection and prognosis, be aggressively pursued.

Lung Cancer—The committee recognizes that lung cancer survival rates are too low, at 15 percent, and it urges the NCI to expand its research into improving lung cancer diagnosis and treatment.

Melanoma—The committee encourages the NCI to

work with advocates and researchers to fund the areas of research identified by the recently developed strategic research plan on melanoma and to use all available mechanisms to target research in those areas.

The committee is aware of recent successes in the therapy of rare forms of melanoma that were the result of basic research on the genetic signature of melanomas, and encourages NCI to include melanoma in The Cancer Genome Atlas consortium to establish a comprehensive map of genetic changes that will point to new therapies for the most common types of melanoma and help identify new markers for classification, detection and risk assessment.

The committee also urges the NCI to promote alliances between industry and academia in the field of melanoma research to foster laboratory and clinical trial consortia that will develop individualized therapies that target pathways or stimulate the patients' own defense system.

The continuing increase in melanoma incidence should spur new efforts to prevent melanoma among high-risk individuals and reach populations at risk for early diagnosis when melanoma is still curable by surgery. Accordingly, the committee encourages the NCI to explore the feasibility of a screening program for melanoma, including focused screening of high-risk individuals.

The committee requests the NCI to report to the Committees on Appropriations of the House of Representatives and the Senate by July 1, 2010, on steps it has taken to implement these strategic investments in melanoma research.

Neuroblastoma—The committee urges continued support for research on high-risk neuroblastoma, particularly as it relates to the development and clinical testing of new therapies for relapse patients.

Pancreatic Cancer—While there has been a continuing decline in mortality rates for many types of cancer, the number of Americans dying of cancer of the pancreas continues to rise.

Despite its highly lethal nature, less than 2 percent of NCI's budget is devoted to what is now the fourth leading cause of cancer-related death. The committee last year urged the NCI to launch a pancreatic cancer-specific research and training initiative. This will require a sustained and targeted effort designed to foster prioritized research immediately as well as build a cadre of researchers over the longer term.

To further these efforts, the committee strongly urges the NCI to develop an action plan for the use of fiscal year 2010 funds and to describe its progress in the

fiscal year 2011 congressional budget justification.

Pediatric Cancer—The committee urges the NCI to further expand and intensify pediatric cancer research, including laboratory research to identify and evaluate potential therapies, preclinical testing, and clinical trials through cooperative clinical trials groups. Such research should include research on the causes, prevention, diagnosis, recognition, treatment, and late effects of pediatric cancer.

Reproductive Scientists Development Program— The committee urges the NCI to continue its partnership with the NICHD with regard to training the next generation of gynecologic cancer researchers.

Social Psychology Research—The committee applauds the NCI's efforts to incorporate innovative social psychological theories into cancer prevention research, and it encourages additional work in this area.

# New HELP Chairman Harkin Urges Cell Phone Precautions

Sen. Tom Harkin (D-Iowa), the new chairman of the Senate Health, Education, Labor and Pensions Committee, earlier this week focused on the alleged links between call phone use and cancer.

Harkin, who inherited HELP chairmanship of the from the late Sen. Ted Kennedy, held the Sept. 14 hearing in conjunction with Sen. Arlen Specter (D-Penn.)

Though there is no hard data connecting cell phone use to cancer, Harkin said such evidence may emerge in the future, and called for precautions. "I'm reminded of this nation's experience with cigarettes," Harkin said at the hearing. "Decades passed between the first warnings about smoking tobacco and the final, definitive conclusion that cigarettes cause lung cancer. If more people had heeded those early warnings, or if we could have established the link between tobacco and cancer more quickly, many lives would have been saved."

Harkin acknowledged that while some studies suggest harm, others see no problem at all. "It is not the intention of this subcommittee to create undue alarm," Harkin said. "I will still use my cell phone after the hearing ends, and I suspect that everyone else here will as well. But one thing we'll want to discuss today is whether we need more NIH research in this area, and how that research should be conducted."

The hearing was pegged to a report by a group of believers in dangers of cell phone use. The report is titled, "Cellphones and Brain Tumors: 15 Reasons for Concern." In the past, as an appropriator, Harkin forced NIH to get involved in research in alternative medicine.

Testifying at the hearing, John Bucher, associate director of the National Toxicology Program at the National Institute of Environmental Health Sciences, said that even though data haven't implicated cell phone use in brain cancer, the U.S. government is funding research in the area.

FDA recently asked the National Toxicology Program to investigate cell phone use. "The NTP is in the initial stages of conducting toxicology and carcinogenicity studies in laboratory animals, using specially designed chambers to provide exposures that simulate those of cell phone users in the U.S.," Bucher said.

In those studies, rats and mice will be exposed to radiofrequency energy from the two technologies (CDMA and GSM) currently used in the U.S. at two frequencies (900 and 1900 MHz), he said. The study is conducted in collaboration with the National Institute of Standards and Technology.

"NIST scientists worked to develop an exposure system that would provide uniform exposures to radiofrequency radiation in unrestrained rodents in the frequency bands used in mobile communications," Bucher said. "This design allows for exposures of up to 20 hours per day, in contrast to the most comprehensive rodent cancer studies carried out to date in Europe using restrained animals, where exposures were only two hours per day. The NIST system consists of 21 separate chambers specially assembled in Switzerland and installed in IIT Research Institute laboratories in Chicago.

"These 21 chambers are essentially shielded rooms with a transmitting antenna radiating radiofrequency fields and rotating stirrers to generate a statistically uniform field," Bucher said.

The pilot studies would be completed in 2012 and reported in 2013. Also, NIH and NCI are conducting research in the area, and NCI is supporting one of the human studies currently underway in Europe.

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