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NIH Director: NCI's Special Authorities "More Of A Negative Than A Positive"

By Paul Goldberg and Kirsten Boyd Goldberg

Special authorities given to NCI under the National Cancer Act of 1971 have been "more of a negative than a positive," said NIH Director Francis Collins.

In an interview with the journal Science, Collins reignited a controversy that predates the federal government's "war on cancer" and brings into question survival of NCI's unique features, including:

• Presidential appointment of the NCI director,

• The institute's authority to submit an annual "bypass budget," a document, which reflects the director's professional judgment of scientific opportunities. At least technically, the document bypasses review by NIH

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In the Cancer Centers:

Medical Consorium To Help Gulf Coast With Environmental Health Threats

A CONSORTIUM of seven medical and public health institutions will expand and connect research projects to help U.S. Gulf Coast communities prepare for and bounce back from weather-related disasters, epidemics and environmental health threats.

Projects by members of the SECURE (Science, Education, Community United to Respond to Emergencies) consortium include development of technology to enhance surveillance systems for early health and environmental warnings and to guide the efforts of first-responders during and after a disaster, arrangement of post-disaster health care, training programs to improve preparedness through community groups and schools, and post traumatic stress counseling.

A grant awarded by the National Center on Minority Health and Health Disparities supports the consortium's focus on the underserved and minority communities who often suffer disproportionately during disasters. "Our goal is to develop a comprehensive approach to disaster preparation and recovery all along the Gulf Coast," said Lovell Jones, the SECURE principal investigator and director of the Center for Research on Minority Health at The University of Texas MD Anderson Cancer Center. "This is the first consortium to examine disaster preparedness and response through the lens of existing health disparities within vulnerable communities," said **Mauren Lichtveld**, the SECURE principal investigator and Freeport

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Collins Cites 2003 IOM Report Critical Of NCI Politicization

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and HHS and is submitted to the president.

• Presidential appointment of members of the National Cancer Advisory Board, which reviews all of the institute's programs.

• The authority of the President's Cancer Panel, which is designed to oversee the "National Cancer Program" and inform the White House about barriers to progress against cancer.

For decades, advocates of the cancer program argued that these authorities serve to coordinate the war on cancer as a government-wide priority. Meanwhile, critics countered that these authorities politicize cancer research, creating a strong fiefdom within NIH, and igniting meaningless battles over turf.

Some argue that politicization has introduced perverse incentives for NCI directors to promise the cure while realizing that none is in sight. So far, the cure—or at least the lightening of the burden of cancer—has been promised for the 1976 Bicentennial, the dawn of the millennium, and 2015.

It's unlikely that Collins' idea would run into opposition from Harold Varmus, the incoming NCI director who is leaving his post as head of Memorial Sloan Kettering Cancer Center to start the new job on July 12.

Varmus's appointment signifies the first time an NIH director—Collins—played a leading role in selecting the head of NCI. Moreover, Varmus served as NIH director from 1993 to 2000, and has regarded the cancer institute as a component of the overall structure of biomedical research.

Sources say Varmus has been on the NIH campus and has met separately with the NCI division directors and other key staff members, who emerged from these meetings with the impression that the new director will start restructuring the institute as soon as he arrives.

It's unclear whether Collins's comments represent venting or a serious legislative agenda. The NIH director declined to discuss the matter with The Cancer Letter.

Collins: "Bypass Budget Has No Effect"

In an hour-long interview with Science, Collins referred to a 2003 Institute of Medicine report that was critical of NCI's special authorities.

"The IOM in their report in 2003 concluded that the special status of the NCI has been more a negative than a positive," Collins said in the interview. "I mean, they were pretty blunt about that.

"So what is it that people are worried about here? Are they worried that somehow not having the ability to submit the bypass budget is going to have a big effect on cancer research? As far as I can tell, the bypass budget has no effect on anything.

"Are they worried that not having a presidentially appointed institute director is going to do damage to the leadership of the institute? Well, look back over time and you decide whether that presidential appointment, which means it becomes a political issue, has been a good thing or not. The IOM thought it wasn't such a good thing. I'll leave you to their opinion.

"So I don't know what the anxiety would really be. I do think frankly that the NCI over the course of the last 30 or 40 years has at times at least been less connected to the rest of NIH than it might have been for its own good and for the good of the rest of us. And now with the science increasingly drawing connections between cancer and other things, there's even more of an argument why we should be working together.

"Take therapeutics. NCI has been the most engaged over the last 10 or 20 years in the development of new therapeutic approaches to cancer, so if we're trying to expand that to other diseases, we need to be connected in that experience. But I think it would also be fair to say that NCI's approach hasn't been 100% successful, either, and if we're going to have a broader NIH effort in therapeutics, they might want to be connected to that, too.

"So I think Harold and I have the same view here,

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that this is a big place with a lot of smart people, and the best outcomes are generally when you don't have walls between parts of the organization that prevent people from learning from each other."

A transcript of the interview is posted at http://www.sciencemag.org/cgi/content/full/328/5982/1090/DC1.

Collins was referring to the 2003 report of the National Research Council and Institute of Medicine of the National Academies. The report, titled "Enhancing the Vitality of the National Institutes of Health: Organizational Change to Meet New Challenges," recommended that Congress should "reassess" the provisions of the Cancer Act.

Because the Act made the NCI director a presidential appointee and allowed the NCI director to submit a budget request directly to the president, "it is possible that an unnecessary rift is created between the goals, mission, and leadership of NIH and those of NCI," the report said.

NCI is the largest of the 27 Institutes and Centers at NIH. "It is not in the interests either of NIH's overall research and training programs, or of NCI, for the NIH director to have such limited authority," the report said.

The report, requested by Congress to study the organization of the institutes, said the NIH director's influence should be enhanced through an increased budget to the director's office and funding for trans-NIH initiatives, and by giving the director the authority to hire and fire directors of the Institutes.

Among the panel's recommendations:

• Congress should establish a formal process to review and act on proposals for changes in the number of NIH institutes and centers, and that process should be used to study two mergers favored by the committee: merging the National Institute on Drug Abuse with the National Institute on Alcohol Abuse and Alcoholism, and the National Institute of General Medical Sciences with the National Human Genome Research Institute.

• NIH-sponsored clinical research in the intramural and extramural programs should be consolidated under a new entity called the National Center for Clinical Research and Research Resources, which would build upon the current National Center for Research Resources.

• The presidentially-appointed NIH director should serve a six-year term unless removed sooner by the president. Whether the director should serve a second and final six-year term should be determined after a review by outside experts and be based on the recommendation of HHS secretary.

• Directors of NIH institutes and centers should be appointed to five-year terms with the option for a second and final five-year appointment. Their performance should be reviewed annually by the NIH director.

• The committee also took issue with the appointment process for the 140 NIH advisory committees. To avoid any perceived politicization of the committee appointment process, participation should be based solely on a person's scientific or clinical expertise, or his or her involvement in relevant issues. Also, a substantial proportion of each Institute's advisory council should consist of people whose primary source of research support is derived from a different Institute, or from outside NIH.

The report is posted at search.nap.edu/books/0309089670/html/.

A Compromise 40 Years Ago

The unusual features of NCI's authorities were the result of a Congressional compromise reached during debates over the legislation in 1971. These debates are chronicled in detail in "Cancer Crusade: The Story of the National Cancer Act of 1971," by Richard Rettig (available at www.iuniverse.com).

At that time, Sen. Edward Kennedy (D-Mass.) took up the cause of cancer advocates led by Mary Lasker, who wanted to take the cancer program completely outside the NIH structure. Kennedy introduced a bill that would have created a National Cancer Authority, whose director would be appointed by the president and would have the mandate to create a comprehensive national plan for "the conquest of cancer." NCI would be transferred to this new agency.

The Nixon Administration opposed the idea of taking NCI out of NIH. Sen. Peter Dominick (R-Colo.) introduced alternative legislation to enhance the nation's cancer research effort.

To break the impasse, Kennedy proposed taking the Dominick bill number and striking everything after the enacting clause, substituting his bill, which had undergone some changes. The bill would establish a Conquest of Cancer Agency as "an independent agency within NIH." The bill passed the Senate with only one vote against it.

In the House, further debate ensued on how independent NCI should be from NIH.

Cancer center directors and cancer advocates argued for giving NCI greater autonomy and authority, while representatives of the biomedical scientific community argued that cancer shouldn't be separated

from the rest of biomedical research. At the time, the MIT biologist David Baltimore cautioned against creating a crash program, because "it will not speed up and may slow down progress, and because the American people should not be misled into thinking that cure for cancer is imminent."

In conference with the Senate and House, compromises kept NCI within NIH, but gave NCI the authority to develop the bypass budget, established the President's Cancer Panel to oversee the cancer effort, formed the National Cancer Advisory Board whose members are appointed by the president, and made the NCI director a presidential appointment.

The legislation also established the comprehensive cancer centers program, a cancer control program, and a carcinogenesis program.

"What does this compromise mean 40 years later?" medical historian Rettig said to The Cancer Letter.

"Clearly, we haven't crossed the Jordan into the Promised Land. In terms of progress against cancer, it doesn't strike me that there has been any beneficial effect from these special authorities. The question is, what kind of time period do we need to test this hypothesis? We've had 40 years. Do we need another 10?"

The question is not terribly significant, Rettig said.

"I am as agnostic on this as I could be in terms of the relationship of the bureaucratic legal budgetary privileges at NCI having any bearing on the science of the clinical care," he said. "Cancer remains a complex and intractable disease. There is a huge disconnect between fiddling with these kinds of bureaucratic dials and what matters in terms of scientific advance that would translate into clinical progress in preventing and treating cancer."

The American Society of Clinical Oncology said the National Cancer Act continues to be important, because it elevates cancer as a distinct priority receiving special attention from the president.

"The National Cancer Act of 1971 established a roadmap to guide the nation's critical investment in biomedical research to address the public health burden of cancer. Congress and the president established important linkages between the NCI (within NIH), the president, Congress, and the American people," ASCO President George Sledge and CEO Allen Lichter said in a joint statement to The Cancer Letter.

The text of ASCO's statement follows:

"At the outset, these authorities helped pave the road and draw attention to the nation's war on cancer. It is clear, however, that continued success for the National Cancer Program requires intense and strategic collaboration throughout the NIH and the federal government—including the Centers for Disease Control and Prevention, the Food and Drug Administration, Centers for Medicare and Medicaid Services, Departments of Defense and Veteran's Affairs, and many more federal agencies. It also requires partnerships with academia, industry, and non-profits. The NCI has used its special authorities to foster these important collaborations throughout the federal government and the private sector. Isolationism is not an option, and President Obama is playing an important role in encouraging his Cabinet heads to find new and innovative ways to work together.

"The National Cancer Act galvanized the American people and set priorities for the nation's biomedical research system. As we gain increasing knowledge of the complexity of cancer biology, presidential attention and involvement in the National Cancer Program is no less important today."

Vincent DeVita, NCI director from 1980 to 1988, said the institute's special authorities were allowed to atrophy by his successors.

"I was the last director to use the special authorities," said DeVita, the Amy and Joseph Perella Professor of Medicine at Yale University and former director of the Yale Cancer Center. "Every NIH director I've known has wanted to refold NCI back in. The only way the act was ever used is for the NCI director to use the authority and do it regardless of all the protests of NIH. I was the last one to do it."

As a result, "the National Cancer Act has been dead for 20 years," DeVita said. "Pretending the bypass budget is actually functional and that the special authorities of the institute actually exist is really silly. In that sense, I agree with Francis."

DeVita said the war on cancer focused NIH on the importance of translational research. "Before the cancer act, NIH was not the slightest bit interested in anything that had to do with the application of the results of research," he said. "The NIH is doing things now it never would have done if not for the pressure put on them by the war on cancer.

"It's dead. The President's Cancer Panel has been dead, the bypass budget is dead, the war on cancer has been dead."

Presidential Appointment

Under the cancer act, the president appoints the NCI director, but the appointment doesn't require confirmation by the Senate.

This made sense in 1971, when the NIH director's job similarly didn't require confirmation. The two jobs—head of NIH and head of NCI were in a position of parity.

However in 1974, the NIH appointment was altered to require Senate confirmation, leaving the NCI director as the only presidential appointee who doesn't have to be confirmed.

Having the support of the president used to be important, DeVita said. "Many of the things you want to do as the NCI director run counter to the NIH, so you find yourself in opposition to NIH," he said. "You could use the fact that you are independent of the NIH and do things you thought were important, as long as you could rely on the president to support you."

This is no longer feasible. "I don't think any president in the last 20 years has even been aware of the fact that the cancer act exists," DeVita said. "The presidential appointment is window-dressing, and actually is detrimental, I suppose. I think [current NCI Director John] Niederhuber would see it as detrimental, because if he weren't a presidential appointee, he might still be a director. Every time a president comes in, you have to face the fact that you might be replaced."

The NCI director's salary has created an odd situation, too. The institute director is the only presidential appointee who receives salary under Title 42 U.S.C., section 209(f) of the Public Health Service Act. HHS has interpreted the statute as allowing certain experts to command a higher salary than ordinary civil service employees.

This quirk makes the NCI director the highest paid presidential appointee. Niederhuber, for example, is paid $247,500. Vice President Joe Biden earns $221,000.

Three of the most recent NCI directors, starting with Richard Klausner, have been Title 42 employees, which technically classifies them as "special consultants." As Title 42 employees, NCI directors earn more than the HHS secretary, the NIH director, and the FDA commissioner, who are presidential appointees confirmed by the Senate.

However, compared to other NIH institute directors, NCI directors are not especially well paid. In recent years, all NIH institute directors switched to Title 42, and Niederhuber's salary makes him only the 57th highest paid NIH employee. The highest paid employee is Anthony Fauci, director of the National Institute of Allergy and Infectious Diseases (The Cancer Letter, Feb. 12).

Political considerations have figured into selection of institute directors. Partisan politics were particularly obvious when George W. Bush appointed Texas urologist and family friend Andrew von Eschenbach to lead the cancer program in 2001.

Von Eschenbach took the vow to end "suffering and death due to cancer" by 2015, and proceeded to restructure NCI around this obviously absurd goal. Not only did von Eschenbach get a promotion to head FDA, but he was able to secure a presidential appointment for his hand-picked successor—Niederhuber.

In an astonishing display of partisanship in 2006, von Eschenbach endorsed the embattled Rep. E. Clay Shaw, a Florida Republican who headed a Congressional group called the 2015 Caucus. The 2015 goal would not be attained "without the kind of leadership that we've experienced from Congressman Shaw," von Eschenbach said on a Florida jaunt (The Cancer Letter, Feb. 3, 2006).

Shaw lost the election.

The Bypass Budget

The proponents of the Cancer Act were first and foremost interested in additional funding for cancer research.

They felt that even with the act's $100-million boost to the NCI budget in 1972, future increases would not be assured. NIH, HHS, and the White House Office of Management and Budget would attempt to hold NCI's funding in line with the other NIH institutes.

Thus, the bypass budget was created to give the institute director the opportunity to speak directly to the president, Congress, and the public to outline opportunities in cancer research that would warrant additional funding.

A strong President's Cancer Panel, led by Benno Schmidt, helped to advocate for the bypass budget during the Nixon administration in the first years following the act. The cancer panel also lobbied successfully for the creation of the National Research Service Awards to support young scientists, and for an increase in NCI staff positions.

While the NCI director submits a bypass budget every year, NIH and HHS submit an entirely different budget proposal for NCI and the other NIH institutes, which bears no relationship to the bypass budget.

The HHS budget is what gets included in the annual president's budget request to Congress. The appropriations committees pay little attention to the bypass budget.

By the mid-1970s, Nixon's promise to give NCI all the money it needed was long forgotten. NCI appropriations have tended to rise in synch with overall

NIH appropriations.

Over the years, the NCI bypass budget grew into a behemoth document containing everything that NCI division directors ever hoped to fund from year to year. The document grew to some 500 pages by 1995.

In 1996, NCI Director Richard Klausner dramatically revamped the document, limiting it to just 78 pages with only the key proposals for major funding increases. Since then, the size of the document has increased slightly, but the emphasis on the key provisions has remained.

"I agree with Francis," DeVita said. "The bypass budget is kind of useless. The bypass budget is a joke. Unless the president wants it, he is not going to take it. The fact that a congressman can ask you during hearings about a figure in the bypass budget is totally meaningless.

"Nobody knows what they are talking about anyhow."

Without Methods

At least on paper, the duties of the President's Cancer Panel include oversight.

According to its statement of duties, "the panel will monitor the development and execution of the activities of the National Cancer Program, and will report directly to the president. Any delays or blockages in rapid execution of the program will immediately be brought to the attention of the president."

This oversight function seems to be co-opted by the fact that the group is funded by NCI and staffed by institute employees.

"It has no real power," said Fran Visco, president of the National Breast Cancer Coalition, who served on the panel during the Clinton administration. "The budget it has and the staff that it has comes from NCI. So if the President's Cancer Panel is supposed to assess the National Cancer Program, it should be able to be independent and critical of the leadership of the cancer program. It's hard to do that when that's who is paying your bills."

In one of the more puzzling episodes in the panel's history, then NCI Director Klausner hired the chairman of the panel, Harold Freeman, to head a new NCI center on health disparities. Freeman ended up drawing an NCI salary while continuing to oversee the institute. On top of that, Freeman was able to keep his NCI funding, his day job at CEO of North General Hospital in Harlem, and his membership on the board of directors of the American Cancer Society (The Cancer Letter, Sept. 15, 2000).

"The President's Cancer Panel is a joke," said DeVita. "Rick Klausner hired the chairman of the President's Cancer Panel to work for him, while he was chairman of the President's Cancer Panel, and nobody noticed. That's ridiculous. You hire the person who is running the panel that's supposed to be providing oversight? Do you see what I mean by being dead? The panel hasn't provided oversight for the NCI."

On paper, the panel has the authority to demand a seat at the table when the new NCI director is selected, DeVita said. As it stands, the most recent selection was made by Collins without any formal process.

"My guess is that they weren't even consulted in terms of the selection of the director," he said. "How dead can you be? Just by a law of Congress, this panel is empowered to oversee the function of the cancer institute; do you tell me that the selection of the new director is not part of that oversight function?"

Unlike the Institute of Medicine, which issues reports based on comprehensive review of evidence and which incorporate prospectively stated procedures, the President's Cancer Panel employs no methods.

It simply convenes meetings, hears testimony, and employs writers to sum it all up. "It's not research that they are doing," Visco said. "It's just reporting what they hear."

Originally, the panel included some powerful players, the financiers Armand Hammer and Benno Schmidt. "They had direct access to the president, and their purpose was to hear from the community what the problems were, and bring issues directly to the president," Visco said.

Recently, President Obama, received a panel report on environmental factors in causation of cancer. The report included practical advice:

—"Family exposure to numerous occupational chemicals can be reduced by removing shoes before entering the home and washing work clothes separately from other family laundry.

—"Storing and carrying water in stainless steel, glass, or BPA- and phosphate-free containers….

—"Exposure to pesticides can be decreased by choosing, to the extent possible, food grown without pesticides or chemical fertilizers and washing conventionally grown produce to remove residues.

—"Adults and children can reduce their exposure to electromagnetic energy by wearing a headset when using a cell phone, texting instead of calling, and keeping calls brief."

The report is posted at http://deainfo.nci.nih.gov/advisory/pcp/pcp.htm

Neither NCI nor IOM could support as these recommendations as science-based. While all of this generated an explosion of unquestioning media coverage, few members of the press appeared to notice that the report lacked a section describing prospectively stated methodology.

That would be because there was no methodology.

In the Cancer Centers:

CHOP Dedicates New Building For Translational Research

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McMoRan Chair of Environmental Policy for Tulane University School of Public Health and Tropical Medicine. "Using research and targeted interventions, we hope to create sustainable programs that empower local communities to protect against real-world threats from natural disasters or environmental incidents, such as the current gulf oil spill."

The SECURE Consortium includes: University of Texas MD Anderson Cancer Center, Tulane University, University of Texas Medical Branch in Galveston, University of Miami, Baylor College of Medicine, Meharry Medical College, and the City of Houston Department of Health and Human Services.

CHILDREN'S HOSPITAL OF PHILADELPHIA dedicated the Ruth and Tristram Colket Jr. Translational Research Building on June 9. Built with an initial gift of $25 million from the Colkets, the 12-story structure houses research programs in pediatric diseases, including the Center for Childhood Cancer Research. The $504 million project encompasses 700,000 square feet—four new laboratory floors, administration and conference space, and a two-story ground floor housing a lobby and cafeteria. There are an additional four stories below grade consisting of infrastructure and laboratory support space.

Professional Societies:

Sledge Takes Office As ASCO President 2010-2011

GEORGE SLEDGE JR., a nationally recognized pioneer in the development of novel therapies for breast cancer, has started duties as president of the American Society of Clinical Oncology.

He will serve as president from June 2010 to June 2011. He was previously president-elect of ASCO. Sledge is the Ballve-Lantero Professor of Oncology and professor of pathology and laboratory medicine at the Indiana University School of Medicine and a physician/researcher at the IU Simon Cancer Center.

Sledge joined the Indiana University School of Medicine faculty in 1983, after completing his residency at St. Louis University and his fellowship at the University of Texas, San Antonio. He received his undergraduate degree from the University of Wisconsin and his medical degree from Tulane University. His research interests include molecular and tumor biology, growth factors, and anti-angiogenic therapy related to breast cancer.

Sledge has been recognized numerous times for his breast cancer research. In addition to being elected to the top position at ASCO, he recently received the Jill Rose Award – Breast Cancer Research Foundation (2007) and the 2006 Komen Foundation Brinker Award for Scientific Distinction.

During the ASCO annual meeting, Sledge appeared on PBS NewsHour discussing highlights of the conference. The segment is available at http://www.pbs.org/newshour/bb/health/jan-june10/cancer_06-07.html.

Advocacy:

LLS To Provide $10 Million For Development Of Estybon

LEUKEMIA & LYMPHOMA SOCIETY and Onconova Therapeutics Inc. are collaborating to support the clinical advancement of Estybon (ON 01910.Na), a compound under development for treating patients with high-risk myelodysplastic syndrome.

Through the partnership, LLS will provide up to $10 million in funding to support a multicenter, randomized, clinical trial of Estybon versus best supportive care in adult patients with MDS who have relapsed or become resistant to azacitidine or decitabine. Onconova expects to start patient enrollment for this study in the third quarter of 2010. This is the first approval-track clinical trial to be supported by the LLS Therapy Acceleration Program.

LLS is taking an active role in accelerating development of novel therapies for patients and has committed substantial, multi-year funding to support this collaboration as part of its Therapy Acceleration Program. LLS is partnering directly with biotechnology companies to improve the timeline for identifying potential breakthrough therapies and advance them along the FDA drug approval pathway.

AMERICAN INSTITUTE FOR CANCER RESEARCH and the World Cancer Research Fund announced a new project that, when completed next year, will provide women who have had breast cancer with better information about how they might be able to improve their quality of life or help prevent breast cancer recurrence.

The project will analyze the published evidence on the impact of diet, physical activity and body fat in women who have been diagnosed with breast cancer. The result will provide the clearest-ever picture on the links between these factors and breast cancer survivorship.

For more information on the Continuous Update Project, visit www.dietandcancerreport.org.

AMERICAN CANCER SOCIETY and the National Palliative Care Research Center are awarding $1.8 million in research grants to researchers at 12 institutions for studies aimed at reducing suffering for seriously ill patients and their family caregivers. The studies will be conducted over the next two years.

NPCRC Pilot Project Support Grant Recipients:

The Research Institute at Nationwide Children's Hospital and The Ohio State University, Cynthia Gerhardt, associate professor of pediatrics and psychology.

University of North Carolina, Laura Hanson, associate professor in the division of geriatric medicine.

Children's Memorial Hospital, Northwestern University, Kelly Michelson, assistant professor and pediatric intensivist.

University of Vermont College of Medicine, Renee Stapleton, assistant professor of medicine.

American Cancer Society Pilot Project Support Grant Recipients:

Oregon Health and Science University, Lissi Hansen, associate professor.

Virginia Commonwealth University Massey Cancer Center, Thomas Smith, the Massey Endowed Professor of Palliative Care Research.

Children's National Medical Center, Maureen Lyon, clinical psychologist and an associate research professor in pediatrics at George Washington University Medical Center.

Northwestern University, Feinberg School of Medicine, Linda Emanuel, the Buehler Professor of Geriatric Medicine and Director of the Buehler Center on Aging, Health & Society.

NPCRC Junior Faculty Career Development Award Recipients:

University of Rochester, Robert Gramling, assistant professor of family medicine.

University of Pittsburgh, Yael Schenker, soon to be an assistant professor of medicine in the division of general internal medicine.

University of California, Los Angeles, Anne Walling, assistant professor of medicine.

Dana-Farber Cancer Institute/Harvard Medical School, Alexi Wright, instructor in medicine at Harvard Medical School and an attending physician in medical oncology at Dana-Farber Cancer Institute.

Science Policy:

NRC, IOM Amend Guidelines For Stem Cell Research

The National Research Council and Institute of Medicine released amended voluntary guidelines for the responsible and ethical conduct of research involving human embryonic stem (hES) cells.

Originally published in 2005 and amended in 2007 and 2008, the 2010 guidelines take into account the expanded role of the National Institutes of Health in overseeing hES cell research and incorporate references to the NIH guidelines issued in 2009.

The new report says where there is overlap between these guidelines and NIH's guidelines, NIH's guidelines supersede.

Also, it identifies three areas in which non-NIH guidelines—such as those recommended by the Research Council and IOM—will continue to be the source of guidance for hES cell research: cell lines derived using nonfederal funds, cell lines derived from embryos produced from sources other than excess embryos created for reproductive purposes, and experiments that mix human and animal cells not currently addressed by NIH guidelines.

Although the advisory committee charged with reviewing scientific advances and amending the guidelines when needed decided to disband after issuing the 2010 guidelines, it noted that there does not seem to be an ongoing neutral forum for the discussion of stem cell issues.

Participants at the advisory committee's final meeting mentioned a need for a similar continuing activity that would allow periodic meetings to discuss knowledge and policy gaps, new problems, and contentious issues surrounding hES cell research.

The report is available at www.nap.edu.