THE CANCER LETTER

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NCI "Garbage Can"—The Director's Office—Gets Makeover In Reorganization Plan

By Kirsten Boyd Goldberg

NCI Director John Niederhuber unveiled a plan to restructure his office, a disparate collection of programs with 550 full-time positions and a budget of $230 million, or five percent of NCI's appropriation.

The reorganization would streamline the executive structure and reduce redundancy, he said. "I am a person who doesn't necessarily like lines and boxes," Niederhuber said in an interview. "We have to have an organizational chart, but we are all inside one big box."

Soon after he was appointed last August, Niederhuber called the director's office "a large garbage can," where programs were "dumped" for

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Capitol Hill:

Frist Helps Fellow Surgeon Von Eschenbach; Senate Votes To Confirm FDA Commissioner

By Paul Goldberg

In his last days as Senate Majority Leader, Bill Frist (R-Tenn.) helped a fellow surgeon by disregarding Senate tradition and calling the vote to confirm Andrew von Eschenbach to the position of FDA Commissioner.

Von Eschenbach was approved in an 80-11 vote, despite two holds placed on his nomination by two Republican Senators, Charles Grassley of Iowa and David Vitter of Louisiana. A third Senator, Jim DeMint (R-SC) removed his hold before the vote.

In his floor statement Dec. 7, Sen. Edward Kennedy called von Eschenbach "a dedicated healer, advocate for public health, and public servant."

"It is long past time to remove the word 'Acting' from the title of Commissioner, and give the FDA the full leadership it needs to confront the challenges ahead. I urge the Senate to approve his nomination."

All but one of the Senators who voted against the nomination were Republican.

In his floor statement, Grassley said von Eschenbach was unsuitable for the job in part because the agency has stonewalled his subpoenas in the investigation of the antibiotic Ketek.

"If this is the type of cooperation I am getting from the FDA under Dr. von Eschenbach, I am very concerned about the cooperation, if any, we will have once he becomes the permanent Commissioner," Grassley said. "And

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Communications, Education To Merge In Office Makeover

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many years and "nobody's taken the lid off and peeked inside" to find out what people did in those programs (The Cancer Letter, Sept. 22).

In the restructuring, the surgical oncologist appears to have opened all the lids, dumped everything out, and put it back together—but differently.

Faced with a budget that requires about a 3 percent cut, Niederhuber asked the entire institute to look through every program to find areas to trim. The review of the director's office began over the past summer.

Niederhuber asked his staff to tell him what went on in those cubicles, several NCI officials said. He met one-on-one with most of the heads of the offices. He set no mandatory budgetary targets. Instead, the emphasis was on improving how the staff functioned, he said.

Some of the resulting changes were suggested by staff members, while other decisions were made within the NCI Executive Committee. The plan was released at a "town hall" staff meeting Dec. 4.

"This has been a high priority for me," Niederhuber said. "I have not done it from a distance. I haven't told other people to do it. I have put myself in the middle of it. I said, 'Let's have a town meeting so that everyone can throw tomatoes and eggs at me, or whatever they want.'"

No foodstuffs were thrown at the meeting, sources said.

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Under the plan, some offices will be moved—on the organizational chart as well as physically—so that offices that need to work together will be grouped together.

Lines of reporting will be altered, enabling Niederhuber to pay more attention to the institute's scientific programs. He plans to hire an executive officer to oversee a large grouping of functions, including financial management, grants administration, human resources, facilities, communications, and education.

The changes Niederhuber described at the staff meeting include:

—Two offices will be merged. The Office of Communications and the Office of Education and Special Initiatives will consolidate to form an Office of Communications and Education, which reports to the executive officer. These offices will join in one location, most likely at Executive Plaza North, a building NCI rents in Rockville, Md., a few miles from the NIH campus.

—Sections within the communications and education offices will be reorganized into five areas: Public Affairs; Research Dissemination and Partnerships (including the Cancer Information Service); Market and User-Centered Research and Evaluation; NCI Content Management Systems; and Communications/Education Systems and Applications.

—A separate Media and Press Relations Office will report directly to Niederhuber.

—The Office of Cancer Complementary and Alternative Medicine has been moved out of the director's office to the Division of Cancer Treatment and Diagnosis.

—The executive officer will have two deputies: one for strategic planning and budget, and one for management and human resources.

—Three offices that need to collaborate but had been separate will be grouped under the deputy EO for strategic planning and budget: the Office of Budget and Financial Management, the Office of Science Planning and Assessment, and the Office of Policy Analysis and Response. The deputy EO also will oversee the Office of Acquisitions and the Office of Grants Administration.

—The deputy EO for management and human resources will oversee the Administrative Resource Centers, the Office of Workforce Development, and the Office of Management Analysis.

—The Office of Liaison Activities was renamed the Office of Advocate Relations, and will continue its programs that serve cancer patient advocates: the Director's Consumer Liaison Group and the Consumer

Advocates in Research and Related Activities program. The OAR will report to a special assistant to the director for external affairs, who reports to Niederhuber. Previously, the liaison office reported to NCI Deputy Director Alan Rabson.

The roles of NCI's three deputy directors have changed under Niederhuber over the past year from direct management to more of an advisory role, sources said. Former NCI Director Andrew von Eschenbach created a "senior management team" with four deputy directors arrayed across NCI's "discovery, development, and delivery continuum" as a layer between himself and the divisions.

Niederhuber returned to NCI's traditional management structure, in which the division directors report to him and work with him through the Executive Committee.

Rabson oversees the Institute Review Office and the Ethics Office. Anna Barker is deputy director for advanced technologies and strategic partnerships, and Mark Clanton is the deputy director for cancer care delivery systems.

Impact On Budget Unclear

It's too early to know how much money the restructuring will save, Niederhuber and other officials said. The budgetary impact will not become clear until the reorganization is completed next year.

"People know I'm impatient, and I want to move forward, but we need to move through the process," he said.

"To relate this to our colleagues outside the NCI who have angst about the budget—as I used to say, 'Give me a shot at this and I can find a couple million dollars [to cut]—$10 million here, $20 million there,'" he said. "Yes, you certainly could. But you would have a lot of unhappy people, and you would pay a price for that—a huge price—in terms of being able to get the work done that we need to do. It's much better for us in terms of trying to be as lean and as efficient as we can, to take this stepwise, to foster a sense of ownership."

Niederhuber said he went through a similar budget-cutting process when he was chief of surgery at Stanford and faced monetary pressures from managed care. Committees were formed to review specific areas of the hospital. Niederhuber served on the operating room committee.

"We had nurses, schedulers, anesthesiologists, orderlies—everybody represented in the room and everybody was responsible for coming up with ideas," he said. "It was amazing how that reduction was owned, rather than enforced. It's a whole different attitude. And we actually found enough money that would make it better for patients.

"That's what we want to create here at NCI," Niederhuber said. "We've got tough times and we've got to reduce our expenses."

Former Director's 2015 Goal, Once The NCI Mission, Deleted From Web Page

By Kirsten Boyd Goldberg

NCI used to be known as the folks who would "eliminate suffering and death due to cancer by 2015."

After nearly three years of battling skepticism, sarcasm and scorn, institute officials recently eliminated the goal from its prominent box on the institute's Web site.

Former NCI Director Andrew von Eschenbach announced the goal two years and 10 months ago and devoted the remainder of his NCI stint to defending it. He was successful in convincing some members of Congress that such progress was possible, and legislators responded by forming the "2015 Coalition" to cheer the allegedly imminent conquest of cancer.

Some members took the goal on the road with them, talking it up to their constituents. Rep. E. Clay Shaw Jr. (R-Fla.) took not only the goal, but also von Eschenbach, for a "Cancer Awareness Tour" (The Cancer Letter, Feb. 3, 2006). Shaw was defeated in the mid-term elections last month.

In late 2005, the goal was featured prominently in the NCI bypass budget document and in the NCI Strategic Plan, where it was called NCI's "Goal and Vision."

In November 2005, cancer center directors led an uprising against the goal. Their words of caution and practicality crushed and nearly killed the "Vision." They accused NCI of over-promising and began to write a report that would present an "honest" picture (The Cancer Letter, Nov. 23, 2005).

That incident left the goal largely dormant. Finally, even von Eschenbach began the process of letting go. He dropped references to "2015." He moved on to become acting FDA commissioner and adopted a new mission promoting "personalized medicine."

By the summer of 2006, von Eschenbach's promise on top of the NCI home page became a historical anachronism. The current institute director, John Niederhuber, acknowledged in an interview that he has

no way to project the date when suffering and death due to cancer would be eliminated (The Cancer Letter, Sept. 22, 2006).

People who take comfort in promises or those who enjoy researching public-relations pratfalls, can drill into the NCI Web site, www.cancer.gov, and turn up a large number of references to the "2015 goal."

For example, one would learn that in 2003, NCI organized focus groups to test the goal's message. Researchers went to Richmond, Va., and San Diego to gather groups they called "the interested public."

The public didn't greet the goal with enthusiasm. One after another, the focus group participants called the goal unrealistic, or in one participant's words, "wishful thinking."

A young woman in San Diego wasn't buying it one bit. "Is that like you just won't have any suffering at all?" she said. A Richmond resident was even more suspicious: "It made me think there is a cure you haven't told us about."

The focus group participants suggested that NCI give the goal extensive alterations, starting by eliminating the word "eliminate." The focus group report is available at http://www.cancer.gov/compendium/public-reaction-2015.pdf.

A New (Old) Mission

In place of the "2015 goal," NCI has posted a new feature on its home page, a box titled, "The National Cancer Act 1971-2006: 35 Years of Progress."

Clicking on the link takes the reader to a page (www.cancer.gov/aboutnci/nca) with information about the National Cancer Act of 1971, which gave the institute greater authorities, including the ability to award contracts and cancer center grants. The Act created the President's Cancer Panel, and made members of the National Cancer Advisory Board and the NCI director Presidential appointments.

The page includes a link to an "NCI Mission Statement," www.cancer.gov/aboutnci/overview/mission.

This apparently "new" mission statement is not pithy and makes no promises, but it describes what the Act actually intended NCI to do:

"The National Cancer Institute coordinates the National Cancer Program, which conducts and supports research, training, health information dissemination, and other programs with respect to the cause, diagnosis, prevention, and treatment of cancer, rehabilitation from cancer, and the continuing care of cancer patients and the families of cancer patients."

Capitol Hill:

Grassley Continues Criticism Of FDA's Von Eschenbach

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every member of Congress should be equally concerned if they take their constitutional duty of conducting oversight of the executive branch seriously.

"This nominee is not likely to serve well because he just doesn't seem to get it," Grassley said. "He has placed media relations over the mission of FDA. First and foremost, he is supposed to do the right thing on behalf of Americans. Dr. von Eschenbach has other interests to serve, and they are not always the interests of John Q. Public."

Von Eschenbach's controversial stint at NCI isn't being held against him.

"At the National Cancer Institute, he led bold new initiatives on the human genome and on nanotechnology," Kennedy said in his statement. "As a physician for patients with cancer and a survivor of cancer himself, he brought an indispensable, patient-centered perspective to the cancer institute, and he'll bring it to FDA as well."

Professional Societies:

ASCO Report Recommends Minimum 5% Increase For NIH

The American Society of Clinical Oncology said NIH should receive a minimum annual funding increase of 5 percent to accelerate the pace of clinical cancer research, and steps should be taken to create a national database of tissue samples essential to cancer research.

The recommendations were included in the society's annual report on advances in clinical cancer research, which identifies the most significant research of the past year. The report identifies six major advances in clinical cancer research, and highlights 26 other notable advances across 10 cancer types and in the cross-cutting areas of cancer prevention and cancer survivorship.

"ASCO's second annual Clinical Cancer Advances report demonstrates that investment in cancer research pays off," said ASCO President Gabriel Hortobagyi, chairman of Breast Medical Oncology at the University of Texas M.D. Anderson Cancer Center. "Over the last year, we've seen significant advances in targeted therapies for hard-to-treat cancers, a vaccine to fight cervical cancer, and new tools in the fast-growing field

of personalized medicine.

"But if we hope to realize the potential of extraordinary new scientific knowledge and accelerate the pace of discovery, we need a new national commitment to cancer research, including greater funding," Hortobagyi said.

The report included these top six advances, not ranked in any order:

—Vaccine approved to prevent HPV infection: The most significant advance in cancer prevention over the last year was FDA approval of a vaccine to prevent HPV infection, which is strongly associated with cervical cancer. The vaccine has the potential to greatly reduce the burden of cervical cancer, which is diagnosed in nearly 500,000 women around the world each year. A 2006 study also found the vaccine effective in preventing HPV-related vaginal and vulvar precancers.

—Targeted therapies prove effective in hard-to-treat cancers: Several studies stand out as advances that will change the standard of care for a number of hard-to-treat cancers. These include studies demonstrating improved survival and response rates in kidney cancer, HER-2- positive breast cancer, and chronic myelogenous leukemia, as well as a study showing that an existing targeted therapy can improve survival in head and neck cancers—the first new treatment for this disease in 45 years.

—First new treatments for kidney cancer in over 20 years: Two new highly-targeted therapies have proven effective against kidney cancer: the investigational drug temsirolimus (CCI-779) was shown to improve survival as first-line treatment for people with advanced, high-risk kidney cancer, and sunitinib (Sutent) was shown to improve progression-free survival and response rates.

—Lapatinib (Tykerb) improves treatment of advanced breast cancer: A new study showed that, for women with advanced HER-2-positive breast cancer that grew despite treatment with trastuzumab (Herceptin), the addition of lapatinib to chemotherapy controlled cancer growth more effectively than chemotherapy alone. These findings give women with HER-2-positive breast cancer a new treatment option. HER-2-positive breast cancer makes up 20% to 25% of breast cancer cases, and is particularly aggressive and difficult to treat.

—Dasatinib (Sprycel) effective in leukemia patients resistant to imatinib: A phase I clinical trial of the new targeted therapy dasatinib in patients with chronic myelogenous leukemia who could not tolerate or had become resistant to the drug imatinib (Gleevec) showed that 92.5% of these poor prognosis patients had no evidence of disease after receiving dasatinib. Following publication of this study, the FDA approved dasatinib for CML in June 2006.

—Cetuximab (Erbitux) is first new treatment for head and neck cancer in 45 years: A multinational study showed that adding cetuximab to standard high-dose radiation therapy for patients with locally advanced head and neck cancer slowed cancer growth and prolonged survival, compared with patients who received radiation therapy alone.

—Genetic test to predict lung cancer prognosis: In a significant advance in the fast-growing field of personalized medicine – which uses genetic information to develop highly tailored approaches to preventing and treating cancer – researchers developed a novel gene profiling test, called the lung metagene model, that can predict which patients with early-stage non-small cell lung cancer are most likely to be cured, and which are most likely to have their disease recur.

"There is much good news from the front lines of cancer research," said Robert Ozols, co-executive editor of the report, chairman of ASCO's Cancer Communications Committee, and senior vice president for medical science at Fox Chase Cancer Center "This report demonstrates the critical role of clinical cancer research in the health of Americans, and the importance of addressing some serious obstacles that could slow the pace of discovery."

Funding Needs Called Urgent

ASCO recommends "urgent action" in two areas over the coming year:

—Increase funding for cancer research: Congress' doubling of the NIH budget between 1998 and 2003 yielded major new discoveries in all areas of biomedical research, including cancer. However, funding has been flat since 2003, and cuts may occur in 2007. ASCO recommends annual minimum funding increases of 5 percent for NIH, beginning in fiscal year 2007. These increases will only be adequate to keep pace with inflation and avoid losing critical ground, but larger increases will be necessary to speed the pace of progress against the disease.

—Increasing access to biospecimens: Human biospecimens play a critical role in the translation of basic science discoveries into potentially useful therapies for patients, by allowing researchers to study the molecular characteristics of cancer cells. However, ready access to biospecimens for use in cancer research has become a major challenge for a number of reasons:

—There are no common procedures for collection

and storage of biospecimens. ASCO recommends implementation and strengthening of guidelines to standardize biospecimen collection, storage, and use, and the development of a national database to enable sharing of information and expertise across research institutions.

—Privacy laws are also hindering access to biospecimens, because researchers are required to get approval from every patient in order to study their tumor samples. ASCO recommends that the Institute of Medicine or a similar body undertake a study of privacy laws to determine their impact on cancer research.

—There is debate over intellectual property rights to biospecimens and related discoveries. ASCO recommends the creation of a centralized database for biospecimens, and a collaborative effort to identify information-sharing strategies that will speed scientific discovery while protecting intellectual property rights.

"Today we face a possible crisis in cancer research," said Roy Herbst, co-executive editor of the report and chief of the thoracic medical oncology section at M.D. Anderson Cancer Center. "Flat federal funding threatens to stall or reverse the progress we have made. While cancer continues to take a tremendous toll, there is a growing bottleneck of new scientific discoveries waiting to be translated into effective therapies for patients, and too many young researchers are leaving the field."

The report, "Clinical Cancer Advances 2006: Major Research Advances in Cancer Treatment, Prevention, and Screening," is available at www.plwc.org/cca2006.

NIH News:

Harold Varmus Papers Added To NLM "Profiles" Web Site

The National Library of Medicine has posted an extensive selection from the papers of molecular biologist and former NIH Director Harold Varmus on its Profiles in Science Web site at http://www.profiles.nlm.nih.gov.

The library collaborated with the University of California, San Francisco, to digitize the papers and make them available. With his long time collaborator, J. Michael Bishop, Varmus developed a new theory of the origin of cancer, which holds that the disease can arise from mutations in certain of our own genes.

"Varmus and Bishop's discovery gave a brilliant new insight into the genetic basis of cancer, of cell growth and differentiation, and of evolution," said NLM Director Donald Lindberg.

The two scientists found that genes in cancer-causing retroviruses are closely related to genes in normal, non-cancerous cells of many different organisms. These normal cellular genes have been preserved over one billion years of evolution and play a key role in controlling cell division and differentiation. Yet, under particular conditions—for example, events during cell division or the rearrangement of chromosomes, as well as external influences like viruses, cigarette smoke, and radiation—they can accumulate mutations that prompt the cell to divide indefinitely, the hallmark of cancer.

The surprising discovery that cancer-causing genes, or oncogenes, are versions of normal cellular genes suggests a common molecular mechanism for the many different types of cancer. It also explains why cancer is most often a disease of old age and accounts for individual differences in the response to carcinogens.

In 1989, Varmus and Bishop shared the Nobel Prize in Physiology or Medicine "for their discovery of the cellular origin of retroviral oncogenes."

Varmus served as NIH director from 1993 to 1999. He is president and director of Memorial Sloan-Kettering Cancer Center in New York.

The online exhibition includes correspondence, laboratory and lecture notes, research proposals, published articles, and photographs from the Harold Varmus papers at UCSF. Visitors to the site can view, for example, Varmus's schematic depictions of gene control in birds, an extensive exchange of letters regarding the naming of HIV, and a photograph of Varmus receiving the Montgomery County (Md.) bicyclist of the year award.

* * *

STEVEN HIRSCHFELD was named associate director for clinical research at the National Institute of Child Health and Human Development. He is a former medical officer at the oncology group at FDA Center for Biologics Evaluation and Research.

* * *

NIH has awarded 58 grants in the Pathway to Independence Award.

The award provides a new opportunity for promising postdoctoral scientists to receive both mentored and independent research support from the same award. NCI had established a similar program in the early 1990s called the Howard Temin Award.

"New investigators provide energy, enthusiasm, and ideas that propel the scientific enterprise towards greater discovery and push forward the frontiers of medical research," NIH Director Elias Zerhouni said.

"We hope that the Pathway to Independence is a bridge that will support new investigators at precisely the point between mentoring and independence that we have seen as a most vulnerable time in the career path. We must invest in the future of our new scientists today if we expect to meet the nation's health challenges of tomorrow."

This announcement is the first of three rounds of awards to be made this fiscal year, with several additional awards from this round to be made in early January. NIH has received almost 900 applications and will issue between 150 and 200 awards for this program this year.

NIH expects to issue the same number of awards each of the following five years. During this time, the NIH will provide almost $400 million in support of the program. All NIH Institutes and Centers are participating in this award program.

The initial 1-2 year mentored phase will allow investigators to complete their supervised research work, publish results, and search for an independent research position. The second, independent phase, years 3-5, will allow awardees who secure an assistant professorship, or equivalent position, to establish their own research program and successfully apply for an NIH Investigator-Initiated (R01) grant. The R01 is the major means by which NIH supports individual scientists in the field.

Clinician-scientists may find this mechanism increasingly attractive because the individual Institutes and Centers have the flexibility to increase the stipend for the mentored phase of the award in a way that is competitive with other training mechanisms, NIH officials said.

Further information about the award is available at http://grants.nih.gov/grants/new_investigators/index.htm.

New Publications:

AMERICAN PAIN FOUNDATION has made available a new publication, "Treatment Options: A Guide for People Living with Pain." The guide includes information about medications, psychosocial interventions, complementary approaches, rehabilitation therapies, and surgical interventions. Print and electronic versions of the free guide are accessible through the foundation's Web site: www.painfoundation.org. . . . **FORMER SEN. EDWARD BROOKE**, Republican from Massachusetts (1967-79), has published a memoir, "Bridging the Divide" (Rutgers University Press) tracing his rise from serving as a soldier in World War II to becoming the first popularly-elected African-American U.S. Senator. He also discusses his treatment for male breast cancer three years ago, at age 83, and his decision to work with advocacy groups to bring more public attention to the disease.

Funding Opportunities:

RFAs Available

RFA-RM-07-006: Limited Competition for Supplements to CTSAs to Plan for Pilot Projects to Apply the National Clinical Research Associates Model in Their Community Engagement Activities. UL1. Application Receipt Date:: Jan. 22. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-RM-07-006.html. Inquiries: Anthony Hayward, 301-435 0791; haywarda@mail.nih.gov.

RFA-RM-07-002: Institutional Clinical and Translational Science Award. U54, K12, and T32. Letter of Intent Receipt Date: Dec 18; Application Receipt Date: Jan. 17. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-RM-07-002.html. Inquiries: Anthony Hayward, 301-435 0791; haywarda@mail.nih.gov

RFA-DA-07-012: The Genes, Environment, and Development Initiative. U01. Letters of Intent Receipt Date: Feb. 15; Application Receipt Date: March 15. Full text: http://www.grants.nih.gov/grants/guide/rfa-files/RFA-DA-07-012.html. Inquiries: Glen Morgan, 301-496-8585; gmorgan@mail.nih.gov.

Program Announcements

PA-07-097: Chronic Illness Self-Management in Children and Adolescents. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-097.html. Inquiries: Ann O'Mara, 301-496-8541; Omaraa@mail.nih.gov.

PA-07-100: Prioritizing Molecular Targets for Cancer Prevention with Nutritional Combinations. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-100.html. Inquiries: Cindy Davis, 301-594-9692; davisci@mail.nih.gov.

PAR-07-020: Understanding and Promoting Health Literacy. R01. Letters of Intent Receipt Date: April 24; Dec. 24; Aug. 22, 2008; April 24, 2009; Dec. 24, 2010 Application Submission/Receipt Date: May 24; Jan. 24, 2008; Sept. 24; May 25, 2009; Jan. 25, 2010. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PAR-07-020.html. Inquiries: Sabra Woolley, 301-435-4589; sabra_woolley@nih.gov

PAR-07-086: Dissemination and Implementation Research in Health. R01. Letter of Intent Receipt Date: April 24; Dec. 26; Aug. 2008; April 22, 2009, Application Receipt Date: May 24; Jan. 24; Sept. 24, 2008; May 22, 2009. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PAR-07-086.html. Inquiries: Jon Kerner, 301-594-7294; kernerj@mail.nih.gov.

PA-07-109: Cross-Disciplinary Translational Research at NIH. R01. Full text: http://www.grants.nih.gov/grants/guide/pa-files/PA-07-109.html. Inquiries: Mark Parascandola, 301-451-4587; paramark@mail.nih.gov.

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