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NCI Anticipates 60% Decline In Number Of New Trials By Cooperative Groups

By Kirsten Boyd Goldberg

A 10-percent budget cut for the NCI-supported cooperative groups would force the institute to eliminate 95 new clinical trials, reduce patient enrollment by 3,000, trigger staff lay-offs in group operations, and shrink statistical centers and tissue banks, NCI Director John Niederhuber said earlier this week.

The cuts would have a chilling effect on clinical research, because only trials yet to be started would be eliminated or postponed, clinical trialists say. Since the groups generally start about 150 trials a year, the projected cuts would eliminate about 60 percent of new trials. The drop in patient accrual would amount to about 11 percent.

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In the Cancer Centers:

DuBois To Leave Vanderbilt For M.D. Anderson; Succeeds Kripke As EVP For Academic Affairs

RAYMOND DUBOIS, director of the Vanderbilt-Ingram Cancer Center, plans to join University of Texas M. D. Anderson Cancer Center as provost and executive vice president for academic affairs by Sept. 1, the center said.

He will succeed **Margaret Kripke**, chief academic officer and executive vice president, who announced her intention to retire from her post last June. She will remain on the M. D. Anderson faculty on a reduced schedule.

"Dr. DuBois is a highly regarded laboratory scientist and clinical investigator, already well known to many at M. D. Anderson. He also is a skilled administrator, who directs one of the nation's most respected comprehensive cancer centers," M. D. Anderson President **John Mendelsohn** said. "He is a terrific choice for M. D. Anderson, which has ambitious plans for the future."

DuBois also is professor of medicine, cell/developmental biology and cancer biology at Vanderbilt. His research interests focus on studies of the molecular and genetic bases for colorectal cancer. He is internationally recognized for elucidating a key role of the prostaglandin biosynthetic pathway in producing inflammatory mediators that promote colorectal cancer. His research facilitated clinical trials targeting this pathway in humans which demonstrated a reduction in colon polyps that are the precursors of cancer.

DuBois will have responsibility for M. D. Anderson's research agenda, (Continued to page 7)

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NIH Guidelines Would Reduce NCI Clinical Research Funds

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Also, the institute's effort to restructure the clinical trials system, begun more than a year ago based on the recommendation of external advisors, could be slowed or stopped for lack of funding.

"We have a tremendous history in this country in our cooperative group mechanism," Niederhuber said. "It's distinctive among the NIH-supported clinical trials programs. It's been the mainstay of our work in taking things forward to proof-of-principle from our discovery process."

In his remarks to NCI's new Clinical Trials Advisory Committee at its first meeting Jan. 10, Niederhuber said NCI is facing a 2.6 percent decline in funding as a result of a budget cut from Congress, taps from NIH and HHS, and mandatory salary and rent increases. Also, budget guidelines set by NIH could impact the funds available for some of NCI's unique programs including cancer centers, Specialized Programs of Research Excellence, and the cooperative groups.

"The pressures of this budget very much affect what we are going to be able to do in the future in the clinical trial arena," Niederhuber said. "This is one of the messages I will be trying to carry over to NIH, as we negotiate with them some of the guidelines they want across the NIH institutes in managing the budget. One of the unique [features] of the NCI is that we have a significant budget line in terms of clinical trial



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research."

Last fall, institute officials advised the cooperative groups to prepare for a "worst-case scenario" of a 10 percent reduction. Some cooperative groups have already begun to lay off staff and eliminate disease committees in anticipation of reductions, sources said (The Cancer Letter, Oct. 27, 2006).

Although fiscal 2007 began last Oct. 1, Congress hasn't finalized an appropriation for NIH and NCI, but passed "continuing resolutions" that keep the institutes operating. Another, year-long, continuing resolution is expected to keep the government operating through the rest of the year (see story on page 4).

"We are almost halfway through the [fiscal] year, and we still don't have a firm handle on what we can confidently spend," Niederhuber said. "The message that I keep trying to get out is that we can't continue to fund the biomedical research enterprise in this up-and-down fashion. We need, in this country, to address the importance of the biomedical research enterprise and to grow that by something that's at least close to inflation each year."

The budget cuts erode the gains made during the doubling of the NIH budget from FY99-03, he said. NIH has lost 8.3 percent in purchasing power since 2004, he said.

NCI supports 10 cooperative groups studying adult cancers and one pediatric cooperative group. Funding for the groups increased from \$97 million in FY98 to \$162 million in FY02, but has since fallen each year to \$146 million in FY06. If NCI imposes a 10 percent cut in FY07, the budget would be \$130.8 million.

About 35 phase III trials and 60 phase II trials would be eliminated or postponed under a 10-percent cut, Niederhuber said.

The groups are distinctive at NIH, because the infrastructure is continuously available to test new therapies, includes researchers who develop and conduct trials at multiple institutions, and the flexible research agenda allows change in strategy in response to scientific opportunities and new discoveries, he said.

Niederhuber said the outlook is unlikely to improve when President Bush releases his budget request for FY08 next month. "It looks as if we are on the same continued decline," he said. "My planning for the future is to do so with the reality that '08, '09 and 2010 are not going to be any better."

Cooperative group chairmen visited Capitol Hill late last fall to lobby for increased funding for NCI and the groups. Over the past 10 years, several reviews of the cooperative group system have concluded that,

while the groups could work more efficiently, the system offers a powerful method of drug testing that is insulated from bias and complements research funded by pharmaceutical and biotechnology companies.

Over the past year and a half, NCI began to implement the recommendations of a report by the Clinical Trials Working Group on more efficient operation of the clinical trials system. The report recommended stronger oversight by NCI as well as several new initiatives to improve trial prioritization, standardize information reporting, and operational efficiency. The working group said that implementing the plan would cost about \$113 million over five years.

NCI was able to provide the \$7.1 million required last year to begin making the changes. For the current fiscal year, \$20.6 million is needed to fund the implementation effort.

James Doroshow, director of the NCI Division of Cancer Treatment and Diagnosis, said the implementation funding is on a list of several high-priority projects that institute officials have not yet funded.

New Clinical Trials Advisory Committee

NCI formed the Clinical Trials Advisory Committee (CTAC)—NCI's first committee in about a decade to be established under the Federal Advisory Committees Act—in response to the recommendations of the working group's report.

Committee members are appointed by the NCI director to provide advice "on the investment of taxpayer dollars in clinical trials and supportive science," according to the committee's charter.

Niederhuber appointed himself chairman of CTAC.

At the first CTAC meeting Jan. 10, committee member Richard Schilsky, chairman of Cancer and Leukemia Group B, noted that the NCI director doesn't serve as chairman of the institute's other advisory boards. "It strikes me as a major difference between this committee and other boards," he said.

Niederhuber said he and the NCI staff "talked a lot about who should chair the board." He thought that by serving as chairman himself, it "sent a strong message" about the importance of clinical research to NCI. "Is that a long-term strategy? I don't know," he said.

Schilsky said Niederhuber's position as chairman could have unintended consequences. "I'm very grateful that you are willing to spend your time chairing this, but it just strikes me as a little bit different from the way the other boards function in that, as the chair of

the board, presumably, whatever the board accepts or votes on—unless you vote against it—would be viewed as something that you endorse, as opposed to the circumstance where the board is chaired by another individual and the recommendations come to you," he said.

"That's a good point," Niederhuber said. "We can talk about it more as we go down the road, and after things get going, it would be perfectly agreeable from my perspective for me to step back and appoint one of the members to be the chair. Your point on the relationship of the board and the leadership of the board to the director is a very important one, and it's a very sensitive kind of relationship.... I think we can come back to this after we get a meeting or two under our belts. I'm willing to make it conform more to the structure of the other boards."

The committee will meet three times a year and consist of 25 members. Ten of the members will hold concurrent membership on either the National Cancer Advisory Board, the Board of Scientific Advisors, Board of Scientific Counselors, or the Director's Consumer Liaison Group. Members will serve four-year terms, or the duration of their terms on the other committees.

Members of the committee are: James Abbruzzese. M.D. Anderson; Peter Adamson, University of Pennsylvania; David Alberts, Arizona Cancer Center; Kirby Bland, University of Alabama at Birmingham; Deborah Bruner, University of Pennsylvania; Jean de Kernion, University of California, Los Angeles; Stephen Grubbs, Medical Oncology Hematology Consultants, Newark, Del.; Bruce Hillman, University of Virginia; Sandra Horning, Stanford University; Susan Leigh, National Coalition for Cancer Survivorship; Gabriel Leung, OSI Pharmaceuticals; Michael Link, Stanford University; Nancy Mendenhall, University of Florida Heath Science Center; Heidi Nelson, Mayo Clinic Rochester; David Parkinson, Biogen IDEC; Edith Perez, Mayo Clinic Jacksonville; Timothy Rebbeck, University of Pennsylvania; Carolyn Runowicz, University of Connecticut; Daniel Sargent, Mayo Clinic Rochester; Richard Schilsky, University of Chicago; Joel Tepper, University of North Carolina, Chapel Hill; Jeffrey Trent, Translational Genomics Research Institute; James Wade III, Decatur Memorial Hospital Cancer Care Institute; James Williams, Pennsylvania Prostate Cancer Coalition.

Ex officio members: Anna Barker, NCI deputy director; James Doroshow, director, NCI Division of Cancer Treatment and Diagnosis; Paulette Gray, director, NCI Division of Extramural Activities; Lee Helman, deputy director, NCI Center for Cancer Research; Richard Pazdur, director, FDA Office of Oncology Drug Products; John Potter, director, U.S. Military Cancer Institute; and Alan Rabson, NCI deputy director. Executive secretary: Sheila Prindiville, director of the NCI Coordinating Center for Clinical Trials.

Capitol Hill:

Scientists Urge Congress To Increase Funding For NIH

By Paul Goldberg

Lobbyists for scientific research are urging Congress to increase funding for NIH and other research institutions, which are being funded through a continuing resolution that is scheduled to expire Feb. 15.

When Republican-led Congress adjourned last month, only two funding bills, those covering the Department of Defense and the Homeland Security Agency, had been passed, and the remaining 10 bills were frozen at the level of the lower of the House or Senate appropriations.

Democratic leaders of the House and Senate appropriations committees said that they intended to pass a year-long continuing resolution in order to concentrate on next year's appropriations process, which is scheduled to begin next month, when the President sends his budget proposal to Congress.

Meanwhile, science groups are hoping to get increases in the context of permanent continuing resolutions.

"During your deliberations on the full-year CR for FY2007, we ask that you take the necessary steps to reverse the current funding trend at NIH, an agency that many identify as the crown jewel of the federal government, by providing an increase in FY2007," Leo Furcht, president of the Federation of American Societies for Experimental Biology, wrote in a letter to Congressional leadership.

The letter, dated Jan. 9., also asked for additional funds of the National Science Foundation and the Department of Energy Office of Science.

Last month, Democratic chairmen of the House and Senate appropriations committees said in a joint statement that their priority would be to get out of the "fiscal mayhem" left by their predecessors.

The Dec. 11 statement by Sen. Robert Byrd (D-W.Va.) and Rep. David Obey (D-Wisc.) leaves open the possibility of adjustments to the continuing resolution, but imposes a moratorium on earmarks.

"We will do our best to make whatever limited adjustments are possible within the confines of the Republican budget to address the nation's most important policy concerns," Byrd and Obey said. "We intend to work with the leadership of both parties in both houses to do what we can to resolve last year's disputes and turn to the challenges facing us in the new fiscal year."

Byrd and Obey said they would alter the process for earmarking. "We will place a moratorium on all earmarks until a reformed process is put in place," the two legislators said. "Earmarks included in this year's House and Senate bills will be eligible for consideration in the 2008 process, subject to new standards for transparency and accountability."

Byrd and Obey noted that over the past 12 years, Congress has been making appropriations in gigantic omnibus bills. "The last time each of the appropriations bills were passed by Congress individually and signed into law on time was 1994—the last time we both chaired the Appropriations Committees," the legislators said. "That is the best way to govern and we are committed to that effort."

Under the continuing resolution, NCI is funded at the level of the House appropriations bill, which is identical to the President's budget proposal and almost \$40 million, or .08 percent, below the fiscal 2006 level. At this level, NCI's budget will have dropped by \$72 million from fiscal 2005 to 2007.

The NCI appropriation in the Senate bill is \$45.4 million higher than in the House bill.

* * *

House Speaker Nancy Pelosi (D-Calif.) banned smoking in the Speaker's Lobby of the U.S. Capitol effective Jan. 10.

"The days of smoke-filled rooms in the United States Capitol are over," Pelosi said in a statement. "Medical science has unquestionably established the dangerous effects of secondhand smoke, including an increased risk of cancer and respiratory diseases. I am a firm believer that Congress should lead by example.

"Recently, the District of Columbia banned smoking in public areas, such as restaurants and other establishments, and I applaud the District for joining the dozens of other major cities, including my home town of San Francisco, in recognizing the need to protect the public from secondhand smoke.

"As Members of Congress, we must be held to a higher standard. We can no longer risk the health of colleagues, staff, pages, reporters and others who pass through the Speaker's Lobby each day."

Letter to the Editors:

Claudia Henschke Responds To Articles On I-ELCAP Study

To The Editors:

The Cancer Letter recently published two issues [Nov. 3 and 22, 2006] that discussed the I-ELCAP

publication in the Oct. 26, 2006 New England Journal of Medicine on CT Screening for Lung Cancer. The first predominantly focused on the notion that since it was not a randomized controlled screening trial, its results were subject to various sorts of bias and could not be used to guide public policy. It also erroneously stated in the first paragraph that I said the National Lung Screening Trial was "unethical." What I did state was that we felt we could not participate because of our evidence on the comparison of CT with chest radiography as published in the Lancet in 1999.

The Nov. 22 issue of The Cancer Letter dealt with the "I-ELCAP soundbites" that we provided to the principal investigators at each of our screening sites along with a copy of our press release. These talking points were developed in open meetings at our 15th semi-annual conference, which included representatives of the National Cancer Institute and the American Cancer Society. The very purpose of the talking points was to avoid having the media make the same mistake as The Cancer Letter, which, instead of focusing on the discussion of the reported results, shifted the attention to a discussion of the NLST.

There is considerable misunderstanding as to our role in support of screening research, including failure to appreciate our dialogue with the NCI director and the NLST leadership prior to initiation of the NLST. Upon our strong urging the NLST protocol was changed to better harmonize the protocols of the two participating groups, ACRIN and PLCO. The PLCO group agreed to use only multi-slice CT scanners and to develop a management protocol while their original plan was to require neither. We also suggested that the ACRIN group be able to screen an equal number of participants as the PLCO while the initial plan called for far less. We continue to have very positive discussions with the current NCI director regarding screening research and how to advance the science in this area.

Our screening study demonstrated a 10-year survival rate for all people diagnosed with lung cancer regardless of stage and treatment, much higher than that usually seen. It is unclear why The Cancer Letter felt it necessary to attack the motivation of the investigators rather than explore the opportunity that these data represent for people at risk of lung cancer. The tone of The Cancer Letter is regrettable as it suggests that it is already known that screening will not be beneficial. We are surprised by this assessment, three years before any publication from the NLST, a study intended to answer this question. Surely the NCI's commitment of over \$200 million to the NLST was made with the hope

that screening would be beneficial. Thus, it would seem that the results of our study should excite great hope for a strongly positive result rather than dismay about its publication.

With regard to the specific criticism that we are trying to hide from being called an observational study, we do clearly reject that characterization. We have published our novel study design in numerous journals over many years. We have explained that our study distinguishes between the component issues of screening—diagnosis and treatment. The diagnostic component provides the information as to how often early diagnosis can be achieved. The comparator group, we believe, should be at the point of treatment, not diagnosis, and the relevant comparison is early treatment vs. late treatment.

The NCI's report of the Lung Cancer Progress Review Group in 2001 stressed that multiple study designs were important and valid and should be facilitated and supported. As best we understand, this is still the official position of the NCI. The importance of different approaches has been amply demonstrated by previous studies on lung and breast cancer screening over the past 40 years and the resulting controversies. The US Preventive Services Task Force recently reviewed the evidence from 6 screening RCTs for lung cancer that involved hundreds of thousands of people. It concluded that none of those trials was of good quality and that they were contradicted by evidence from nearly all of the case-controlled studies. As they could not balance the risks and benefits related to screening, it was suggested that, "If screening is being considered, doctors and patients should discuss the pros and cons of screening before going ahead with x-ray, CT scan, or sputum cytologic examination to screen for lung cancer."

Screening RCTs for breast cancer even led to congressional hearings, "Making Sense of the Mammogram Controversy: What Women Need to Know," on February 28, 2002. These hearings focused on providing women with appropriate information, since statisticians could not agree on the interpretations of those RCTs. Ultimately it was agreed, primarily based on testimony by clinicians, that screening did result in early diagnosis, leading to early treatment. The logical conclusion of a mortality benefit was inescapable, given that earlier treatment has been shown to be superior to later treatment. Indeed the summary statement of the hearing by the chairwoman of the conference, Senator Barbara Mikulski, was:

"First of all, what we see is that the biostatisticians

disagree. That is clear. And they will continue to look at data and analyze it. Clinicians, those who have the lives of patients in their hands, do not disagree [,] that clinicians agree and recommend in the most enthusiastic, unabashed, and unqualified way that we follow the existing guidelines that have been established by the National Cancer Institute, recently reaffirmed by the Preventive Services Task Force at HHS, and have also been the longstanding recommendations of the American Cancer Society."

A serious discussion regarding evaluation of screening for cancer is long overdue. We welcome all valid scientific debate.

Claudia Henschke

Principal Investigator International Early Lung Cancer Action Program Professor of Radiology Weill Medical College of Cornell University

Response from The Cancer Letter editors:

We disagree with Claudia Henschke's assertion that we made a "mistake" by discussing the National Lung Screening Trial in stories about the I-ELCAP publication.

While Henschke and her supporters argued that the findings of her single-arm study are sufficiently "compelling" to justify a change in health policy, we quoted experts who pointed out that a change in policy would be premature, and that more reliable answers would emerge in NLST, a randomized trial, which is currently being conducted by NCI.

Nowhere in our coverage do we suggest that "it is already known that screening will not be beneficial." Instead, the stories pointed out that the jury is still out on CT screening for early-stage lung cancer, that lead-time bias could account for Henschke's results, and that patients could be harmed by screening and subsequent interventions.

We find it difficult to understand Henschke's claim that her statements on NLST were conveyed inaccurately. "[The Cancer Letter] erroneously stated in the first paragraph that I said the National Lung Screening Trial was 'unethical,'" she writes. "What I did state was that we felt we could not participate because of our evidence on the comparison of CT with chest radiography as published in the Lancet in 1999."

If there is a distinction here, it continues to elude us. When a clinical researcher states that she believes that one of the modalities compared in a randomized trial is inferior to the other and will result in harm, is she not saying that she believes that the randomized trial is, in her opinion, unethical?

Over the years, many scientists—and many journalists—have heard Henschke state that she regards a randomized trial comparing spiral CT with chest X-ray as unethical. Here are several examples of her statements, directly quoted or summarized in the press:

—"If you really believe that spiral CT inverts the usual pyramid and picks up mainly early-stage cancers, how could you possibly enroll patients into a randomized trial? How would you write the informed consent?" Henschke said to JNCI six years ago. This led the writer to conclude that "for Henschke and others close to the developing technology, it is unthinkable to consider performing a randomized controlled trial." (JNCI, April 19, 2000).

—The New York Times appears to have heard the same message last year. "[Henschke] questions whether [NLST] will be definitive," the Times reported on Oct. 31, 2006. "It may be too short, and even 50,000 patients may not be enough, she said. She has also challenged the study on moral grounds, asking if it is ethical to give some patients only chest X-rays when it is already known that CT picks up more tumors."

—The Cornell Daily Sun, too, reported similar comments. "[Henschke] said it would be unethical to offer simple chest X-rays to one group, as her earlier study showed that 83% of the Stage I cancers are missed on chest X-ray, while the clearly more effective CT scans are given to the other group," the paper reported on Nov. 9, 2006. "If this were the case, the former group would be at a clear disadvantage by not being screened using the more advanced technology."

—In a 2003 report on early detection, the National Cancer Policy Board of the Institute of Medicine said that a paper by Henschke has "called [randomized] trials unethical, as this would be the case if spiral CT were clearly efficacious and such trials were simply testing a new or altered protocol."

The Cancer Letter stands by its coverage.

In Brief:

Clanton Resigns From NCI For Post At Cancer Society

MARK CLANTON, NCI deputy director for cancer care delivery systems, resigned from NCI in December to join the American Cancer Society as chief staff medical officer for the High Plains Division and the Hawaii Pacific Corp.

In his two and one-half years at NCI, Clanton provided leadership to the NCI Center to Reduce Cancer

Health Disparities and Office of Science Planning and Assessment, and was involved in major conferences on tobacco control, international research organizations, and complementary and alternative medicine.

"Since he arrived at NCI, Mark has contributed in bringing his expertise to bear on expanding and enhancing NCI's research portfolio to have a greater impact on cancer care delivery," said NCI Director John Niederhuber. "Mark's high level of dedicated service to cancer patients and communities in need was epitomized by his volunteering to lead NCI's efforts to bring relief to displaced cancer patients and others in the wake of Hurricanes Katrina and Rita last year. He and many others from NCI, NIH, and HHS were true heroes by bringing in the resources and personnel to ensure the safety and well-being of medical personnel and patients in the area."

Prior to joining NCI, Clanton was chief medical officer of Blue Cross Blue Shield of Texas.

At ACS, Clanton will provide strategic direction on medical and scientific issues in the six-state area including Nebraska, Missouri, Kansas, Oklahoma, Texas, and Hawaii.

In the Cancer Centers: DuBois Also Named Provost

(Continued from page 1)

programs, resources and space; educational programs; and all activities related to the appointment, resourcing, and mentoring of faculty.

He will be the first executive to have the title of provost at M. D. Anderson, a term in use at most universities to describe the highest-ranking academic officer. "We have chosen this title to reflect the importance of our expanding research endeavors, our degree-granting status, and the climate of scholarship and discovery that we strive to achieve in all mission areas," Mendelsohn said.

DuBois will oversee a research program that in 2006 had expenditures of \$410 million, a 95 percent increase over the last five years. Federal research grants totaled \$182 million, including 10 Specialized Programs of Research Excellence grants from NCI. He also will lead M. D. Anderson's growing domestic and international training programs, including 15 affiliations with global sister institutions, research and clinical fellowships and residencies, graduate and bachelor degree programs and other special educational programs. In 2006, more than 4,300 students, fellows, visitors and health care professionals received training

at M. D. Anderson.

A native of Runge, Tex., DuBois received his bachelor's degree in biochemistry at Texas A&M University. He earned his medical degree from The University of Texas Health Science Center at San Antonio, preceded by a doctorate in biochemistry from The University of Texas Southwestern Medical Center at Dallas. After a residency and fellowship at Johns Hopkins University, he joined the Vanderbilt faculty 15 years ago. He has been director of the Vanderbilt-Ingram Cancer Center for the last two years.

DuBois plans to move his laboratory from Vanderbilt to M. D. Anderson. He is principal investigator on three NIH research grants, including a MERIT award from the National Institute of Diabetes and Digestive and Kidney Disease.

Vanderbilt now joins five other comprehensive cancer centers that are searching for new directors: University of Minnesota, University of Alabama at Birmingham, Johns Hopkins, Georgetown University, and Fox Chase Cancer Center.

Obituary:

Susan Molloy Hubbard, Former Director, ICIC

Susan Molloy Hubbard, former director of NCI's International Cancer Information Center, died of atherosclerotic cardiovascular disease Dec. 11 at her home in Potomac, Md. She was 60.

Hubbard was instrumental in starting NCI's PDQ cancer information database and Cancernet Web site. She received several awards for her work, including an Outstanding Alumni award from the University of Connecticut, the U.S. Public Health Service Distinguished Service Medal, and a Good Housekeeping Award for Women in Government from Good Housekeeping magazine.

Hubbard was born in Bridgeport, Conn., and received a degree in nursing from the University of Connecticut in 1967. She worked in a cancer unit at Yale-New Haven Hospital and became a research nurse at NIH in 1979. She served as chief of the Scientific Information Branch in the NCI Division of Cancer Treatment. She received a master's degree in public administration from American University in 1993.

She wrote or contributed to more than 170 articles on oncology nursing, information technology and health communication. She retired as director of the International Cancer Information Center in 2002, and as a captain with the Public Health Service.



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