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Drug Shortage A Boon For Levoleucovorin; Price Is 60 Times Higher Than Leucovorin

By Paul Goldberg

The supply of leucovorin is running low.

The drug, widely used with 5-fluorouracil in the treatment of colon cancer, has been made by two generic drug companies in the U.S.: Teva Pharmaceuticals USA and Bedford Laboratories.

Did one or both of these firms drop the ball on production of the ultra-cheap drug, which was approved in 1952 and has the average sales price of 89.4 cents for a 50-milligram vial? Clearly, the answer is yes, but beyond that, the picture gets murky. Bedford blames Teva, and Teva blames Bedford.

Regardless of who is to blame, the shortage of leucovorin is opening the door for a more expensive, branded drug, levoleucovorin, sold under the trade name Fusilev by Spectrum Pharmaceuticals Inc.

"We've definitely seen some benefit from the leucovorin shortage," said Paul Arndt, manager of investor relations at Spectrum. Arndt declined to

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Transition:

Daschle Nomination For HHS Secretary Held Up in Senate Finance Committee

By Kirsten Boyd Goldberg

HHS Secretary-Designate Tom Daschle sailed through a confirmation hearing Jan. 8 in the Senate's Health, Education, Labor and Pensions Committee. However, his confirmation hit a snag in the Senate Finance Committee, where the Republican staff is examining his tax records and his association with an education-loan provider.

No impropriety has been suggested, but the group, called EduCap Inc., has faced questions about its lending practices and possible abuses of its charity status.

Bush's HHS Secretary Michael Leavitt will step down at noon Jan. 20. Assistant Secretary Charlie Johnson will serve as acting secretary until Daschle is sworn in, according to an email sent to department employees last week.

At the Senate HELP Committee hearing, Daschle said it is the role of HHS to ensure that "all Americans have health care," though 46 million are uninsured. If confirmed, Daschle also will lead a new White House Office of Health Reform.

Daschle pledged to restore public trust in the FDA. "I will send a clear message from the top that the President and I expect key decisions at the FDA

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Generic Leucovorin Makers Blame Each Other For Shortfall

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discuss projected sales gains. "We'll find out in a couple of months, when we report our financial earnings," he said.

Levoleucovorin was approved last March as rescue for patients receiving high-dose methotrexate therapy for osteosarcoma, and the company is seeking the colon cancer designation.

The drug will cost 58.5 times as much as the garden-variety leucovorin. In the widely used FOLFOX and FOLFIRI regimens, a patient receives about 800 mg of leucovorin, which at the average sales price compiled by the Centers for Medicare and Medicaid Services, costs $14.30 for a single course of treatment. Substitute levoleucovorin, and the price shoots up to $836.78.

Patients on these regimens are treated every two weeks for many months.

As a result of the shortage, private payers are grudgingly agreeing to pay for levoleucovorin.

"Oncologists have called to say 'I can't access any more leucovorin. I've got to use levo, will you cover it?'" said Lee Newcomer, business leader of Oncology Services for UnitedHealthcare of Minneapolis. "And we will cover it on a temporary basis until the shortage is resolved. What we won't do is cover levo as a long-term substitute. As soon as this shortage is over, this drug is going to lose coverage, because there is no reason for it."

CMS hasn't made a determination on paying for the drug.

The science behind levoleucovorin is straightforward. Regular leucovorin is a racemic mixture of dextro- and levoleucovorin. Though dextroleucovorin has no biological activity, as a practical matter, it's cheaper to make a racemic mixture than to isolate out the stereoisimer.

"It's not even clear to me why somebody decided to make levoleucovorin, but they did, and they experimented to see if it was better, and, gosh-golly-gee-wiz, it's not," said Leonard Saltz, a colorectal cancer expert at Memorial Sloan-Kettering Cancer Center, who is pondering the leucovorin shortage in his role as chair of Memorial's Pharmacy and Therapeutics Committee. "Just that basically 50 mg of levo equals equals 100 mg of racemic, because 100 mg of racemic has 50 mg of levo in it."

There are other alternatives for leucovorin: capecitabine used as a single agent as a substitute for 5-FU, and the oral version of leucovorin. However, these agents have different toxicities, cost more, and—in the case of oral leucovorin—present the practical problem of asking patients with nausea to swallow a very large number of pills.

Also, unlike levoleucovorin, these agents are listed in drug compendia, and would be automatically covered without being flagged for Newcomer and his counterparts at CMS and other health plans. Spectrum attempted to get a listing for its drug in the American Hospital Formulary Service Drug Information compendium.

After a review, AHFS concluded: "Given the lack of established difference in either the safety or efficacy profile of the levoleucovorin-fluorouracil regimens relative to the racemic leucovorin-fluorouracil regimens, as well as the lack of consistent pharmacokinetic data demonstrating an adverse effect of the racemic leucovorin formulation on the pharmacokinetics and biologic effects of the *l*-isomer, the clinical benefit of using levoleucovorin in combination with fluorouracil for the treatment of advanced-stage colorectal cancer is not fully established."

The drug was given the classification of "C," or "Not Fully Established (Unclear risk/benefit, equivocal evidence, inadequate data and/or experience)." The review is posted at www.ahfsdruginformation.com/off_label/tables/determination_levoleucovorin.pdf.

Though next to lowest, this classification doesn't preclude local Medicare administrators from paying for the drug.

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Founded Dec. 21, 1973, by Jerry D. Boyd.

Recently, the American Society of Clinical Oncology sent an email to its members, describing all options for coping with the leucovorin shortage. The email, dated Jan. 8, did something Spectrum sales force could not. It mentioned an off-label use of levoleucovorin to all of America's oncologists:

"Unlike leucovorin, levoleucovorin is not FDA-approved for use in colorectal cancer or other malignancies (with the exception of use for rescue after high-dose methotrexate therapy in osteosarcoma). However, it has been used off-label in the treatment of malignancies, as a substitute for leucovorin, though noninferiority in terms of efficacy has not been tested either for metastatic disease or adjuvant therapy."

Spectrum's Arndt said the company doesn't keep track of the drug's utilization and doesn't know how much of the drug is used off-label.

"If you read the ASCO letter, they said, keep in mind that levoleucovorin is not approved for colorectal cancer, but you can use it in place of leucovorin, which is used in colorectal cancer," Arndt said.

The company filed a supplemental new drug application for the colorectal cancer indication last October.

FDA doesn't consider the issues of cost of the therapies it approves. Since the agency didn't seek advice from the Oncologic Drugs Advisory Committee, the agent's initial approval last March was apparently regarded as non-controversial.

The drug is marketed in Europe by sanofi-aventis and Wyeth Pharmaceuticals, and in the Far East by Takeda Pharmaceutical Company Ltd.

Spectrum said it sold about $2 million worth of levoleucovorin between the product's launch last August and the end of the year.

Substitution Option: No Leucovorin At All

After four decades of looking for the optimal 5-FU regimen, gastrointestinal oncologists left many questions unanswered.

Some say that the requirement to use leucovorin as a potentiator is one of these unanswered questions, and that one option is to use no leucovorin at all, some experts say.

"People got very comfortable with leucovorin," Saltz said. "We had only 5-FU for the sixties and well into the seventies. And then the leucovorin idea looked so good in the laboratory and encouraging in phase II studies, but the phase II studies allowed a lot more toxicity, because we weren't giving just 5-FU, so it gave us a comfort level to push people a bit harder, and with that we did get better efficacy. How much we could do the same thing by just giving more 5-FU is not clear to me, and I suspect that we could do just as well with 5-FU. Up until this shortage it hasn't been an issue.

"My reading of the old studies of 5-FU/leucovorin are that leucovorin increases both the efficacy and the toxicity of 5-FU, and it's not at all clear to me that it increases the therapeutic window," Saltz said. "My sense is, if I can't get leucovorin, I am going to give a little more 5-FU. But I don't know exactly how much to recommend."

Saltz said MSKCC is going to consider that option.

Shortages of old drugs aren't new in oncology. In recent years, there have been shortages of chemotherapies including 5-FU, vinblastine, cisplatin and carboplatin, as well as dexrazoxane, a cardioprotectant used with anthracyclines. In fact, the latest cisplatin shortage was just announced by FDA. Cisplatin is made by Bedford, Teva, and APP Pharmaceuticals.

In some cases, shortages have been turned into money-making opportunities for generics. Three years ago, procarbazine, trade name Matulane, a cheap old drug for the treatment of lymphoma and brain tumors, disappeared from the market, only to return with an 84-fold price increase (The Cancer Letter, May 13, 2005).

Spectrum's Arndt said he had no idea what caused the shortage.

Bedford, a division of Ben Venue Laboratories, issued a statement in which it acknowledged "interruptions in the supply" of its leucovorin, attributing it to construction of a new production plant.

However, the company deflected the blame for the shortage of leucovorin.

"Throughout 2008, Bedford Laboratories supplied approximately half of the total leucovorin injectable market," the company said. "At this market equilibrium, supply was consistent without interruption. Unfortunately, increased demand and/or shortages from other suppliers has now led to a backorder."

The company said it's expediting manufacturing "to meet increased product demand," but construction of its plant will "in the short term" preclude the company from ramping up production.

Teva officials said they haven't slowed down production. On the contrary, production has been ramped up since the shortage was first reported.

"In the late fall, we started to get calls from customers asking if we could supply them with leucovorin as they were unable to get it from their

regular supplier," said Jeffrey Herzfeld, senior vice president general manager of Teva Health Systems. "Since then, we have been trying to satisfy most of the market by ourselves.

"Although we had no initial problems with supply, we went on the backorder ourselves as the market started to perceive a shortage, and that ran us into the backorder while we were continuing to ramp up," Herzfeld said.

FDA first included leucovorin in its drug shortage list on Nov. 20.

Teva said it has taken other products off the production line to order to increase leucovorin production capacity. "We had people in over the holidays, when we normally shut down, to continue to make additional product and make sure we are getting it released," Herzfeld said. "Without knowing if anyone else will come back into the market, we anticipate that at our current pace, in a very short time, we will be making enough on a regular basis to supply most of the market."

Usually it takes about 40 days to make a batch of leucovorin, but the process can be expedited to 22 days.

The drug has to go through a freeze-drying process, followed by at least two weeks of testing for sterility and the presence of microbes. Packaging, inspection and shipping to distributors takes additional time.

"We released three additional batches this week," Herzfeld said. "We have some more scheduled for release next week."

According the FDA's drug shortage information, a similar situation is observed with cisplatin: Bedford's production of that drug is entirely on backorder with no projection for release, Teva is scrambling to produce more drug in the next few weeks, and APP has drugs available, but is forced to allocate them.

Drug shortages are posted at www.fda.gov/cder/drug/shortages/#Current.

FDA News:

FDA Allows Reprint Distribution On Unapproved Uses Of Drugs

By Paul Goldberg

FDA earlier this week published the final version of a guidance on dissemination of reprints of papers on off-label uses of drugs, biologics and devices.

The document, published Jan. 12, is largely unchanged, compared with the draft version that was released last February (The Cancer Letter, Feb. 22, 2008).

In one of the changes, the final version of the guidance allows distribution of reprints discussing historically controlled studies, pharmacokinetic and pharmacodynamic studies, and meta-analyses testing a specific clinical hypothesis. The draft guidance classified such documents as inappropriate.

Another change, aimed at regulating ghostwriting, requires separate disclosure of conflicts on the part of authors even if they are not cited in disseminated materials.

While the pharmaceutical industry was generally pleased with the document, its critics described it as harmful to public health and urged immediate reconsideration by the incoming Obama administration.

"We are pleased that the FDA has confirmed the importance of medical journal articles and reference texts that contain information not in approved product labeling, and has clarified how this medical information can be provided to health care professionals by companies," said Alan Bennett, an attorney with Ropes & Gray, who specializes in pharmaceutical issues.

"Physicians can and do prescribe drugs for unapproved uses, a practice that is appropriate and widespread," Bennett said in an email. "Peer reviewed journal articles on unapproved uses are an important source of information for providers and helps them make informed treatment recommendations to their patients."

Henry Waxman, chairman of the House Committee on Energy and Commerce, said the guidance will need to be reconsidered.

"In the final hours of this administration, political appointees at FDA have given drug companies a long-coveted parting gift," Waxman said in a statement.

"Despite revelations that drug companies manipulate medical journal articles to exaggerate the benefits and downplay the risks of their drugs, the guidance gives companies a green light to promote unapproved uses of their products by handing out these journal articles," Waxman said. "This fundamentally undermines the requirement that companies prove to FDA that each new use is safe and effective.

"I hope this policy will be carefully re-examined by the new administration."

Guidance Provisions

Under the guidance, scientific articles should be:

—Published by an organization that has an editorial board that uses experts who have demonstrated expertise in the subject of the article under review

by the organization and who are independent of the organization to review and objectively select, reject, or provide comments about proposed articles; and that has a publicly stated policy, to which the organization adheres, of full disclosure of any conflict of interest or biases for all authors, contributors, or editors associated with the journal or organization;

—Peer-reviewed and published in accordance with the peer-review procedures of the organization; and

—Not be in the form of a special supplement or publication that has been funded in whole or in part by one or more of the manufacturers of the product that is the subject of the article.

A scientific or medical reference publication that is distributed should not be:

—Primarily distributed by a drug or device manufacturer, but should be generally available in bookstores or other independent distribution channels (e.g. subscription, Internet) where medical textbooks or periodicals are sold;

—Written, edited, excerpted, or published specifically for, or at the request of, a drug or device manufacturer; or

—Edited or significantly influenced by a drug or device manufacturer or any individuals having a financial relationship with the manufacturer.

Letters to the editor, journal abstracts, and reports of phase I trials cannot be disseminated, the guidance states.

Reprints should be:

—Unabridged and not marked, summarized, or characterized by the manufacturer in any way;

—Accompanied by a comprehensive bibliography of previously published studies of the off-label use and, if applicable, by a copy of a representative publication that comes to a different or contrary conclusion regarding such use; and

—Distributed separately from information that is promotional in nature.

In a the ghostwriting provision, the reprints will now have to disclose "any author known to the manufacturer as having a financial interest in the product or manufacturer or who is receiving compensation from the manufacturer, along with the affiliation of the author, to the extent known by the manufacturer, and the nature and amount of any such financial interest of the author or compensation received by the author from the manufacturer."

The guidance is posted at http://www.fda.gov/oc/op/goodreprint.html.

FDA, Companies Don't Collect Conflict Of Interest Information

By Paul Goldberg

An audit by the HHS Office of Inspector General found that FDA and drug companies largely ignore their obligation to collect information on conflicts of interest on the part of clinical investigators.

OIG reviewed financial forms, attachments, and agency review notes for all 118 marketing applications approved by the agency in fiscal 2007, finding that less than one percent of investigators disclosed a financial interest.

The report found that among clinical investigators listed in financial forms, 1 percent disclosed at least one financial interest. This represents 206 of the 29,691 clinical investigators listed in financial interest forms. Of these 206 clinical investigators, almost all disclosed only one financial interest, with a few disclosing two or three financial interests.

Most disclosed financial interests were payments from sponsors. Seventy-seven percent of disclosed financial interests were for payments from sponsors. Most payments were for consulting services or general honoraria.

Though not required, 53 percent of payment disclosures included a specific dollar amount. The median reported payment was $47,252, almost twice the $25,000 minimum payment reporting threshold. The highest reported payment was a sponsors' payment of $3.9 million to a clinical investigator's affiliated institution.

The reports other findings include:

—FDA cannot determine whether sponsors have submitted financial information for all clinical investigators. FDA cannot determine whether sponsors have submitted complete financial information for all clinical investigators because it does not have a complete list of clinical investigators. In addition, FDA does not use onsite inspections to confirm that submitted financial information is complete.

—Forty-two percent of FDA-approved marketing applications were missing financial information. Twenty-three percent of approved marketing applications were missing a certification or disclosure form or required attachments. In 28 percent of marketing applications, sponsors used the due diligence exemption to indicate that they were unable to provide complete financial information. Although allowed by regulation, sponsors' use of the diligence exemption results in no financial information for FDA

reviewers. Some marketing applications had both missing attachments and the due diligence exemption was marked.

—**FDA didn't document a review of any financial information for 31 percent of marketing applications.** When FDA reviewers used a review template, they were more likely to document a review of financial information.

—**Neither FDA nor sponsors took action for 20 percent of marketing applications with disclosed financial interests.** In 20 percent of marketing applications, FDA reviewers did not take action and sponsors did not indicate that they minimized potential bias during the clinical trials. For over half of these marketing applications, reviewers did not document a review of financial information. In addition, when FDA did take action, their actions were inconsistent.

According to the report, FDA rejected the OIG recommendation that the agency require sponsors to submit financial information for clinical investigators as part of the pretrial application process.

Collecting financial information before a clinical trial starts is the sponsors' responsibility, the agency objected. Also, the agency said that collection and review of financial information would be burdensome for both the industry and regulators.

"Despite this important role for sponsors, FDA has no mechanism in place to ensure that sponsors are in fact collecting financial information before beginning clinical trials," the report states. "Pursuant to regulation, FDA already requires sponsors to collect financial information before the start of clinical trials."

The OIG report is posted at http://www.oig.hhs.gov/w-new.asp.

In recent months, Congress has been similarly concerned about conflicts of interest on the part of extramural investigators receiving NIH funds and about the government's role in managing such conflicts.

Professional Societies:

ASCO Members Elect Sledge As President For 2010

GEORGE SLEDGE JR. was elected president of the American Society of Clinical Oncology for a one-year term beginning in 2010. He will take office as president-elect during ASCO's annual meeting in Orlando in June.

Sledge is the Ballve-Lantero Professor of Oncology and professor of pathology and laboratory medicine at the Indiana University Melvin and Bren Simon Cancer Center. He joined Indiana University 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.

ASCO elected six members to its board:

Clifford Hudis, treasurer. Hudis is chief of the Breast Cancer Medicine Service at Memorial Sloan-Kettering Cancer Center.

Eduardo Cazap was elected to a non-U.S. oncology seat. He is president of the Latin American and Caribbean Society of Medical Oncology and president of the International Union Against Cancer.

Susan Cohn was elected to the pediatric oncology seat. She is director of Pediatric Clinical Sciences at Comer Children's Hospital in Chicago and professor of pediatrics at the University of Chicago.

Lynn Schuchter was elected to an undesignated specialty seat. She is director of the Clinical Research Unit at the Abramson Cancer Center at University of Pennsylvania and head of the center's melanoma program.

Everett Vokes was elected to an undesignated specialty seat. He is the John Ultmann Professor in the Departments of Medicine and Radiation Oncology and serves as director of the section of hematology/oncology and co-deputy director of the cancer center at the University of Chicago.

Peter Yu was elected to a community oncology seat. He is a physician in the hematology department of the Camino Medical Group, which is affiliated with the Palo Alto Medical Foundation.

New members of ASCO Nominating Committee: **Scott Lippman**, chairman of the Department of Thoracic/Head and Neck Medical Oncology and a Professor of Cancer Prevention at the M. D. Anderson Cancer Center; and **Monica Morrow**, chief of Breast Service in the Department of Surgery at the Memorial Sloan-Kettering Cancer Center.

Cancer Will Be Leading Cause Of Death In 2010, Report Says

Cancer will become the leading cause of death worldwide in the year 2010, and the countries low- and middle-income countries will shoulder a greater cancer burden than industrialized countries, the International Agency for Research on Cancer said in a report.

The 500-page report, IARC's second such publication since 2001, states that increasing tobacco use, obesity and other woes spreading from Western societies are rapidly making cancer a growing global.

The cancer burden has doubled globally between 1975 and 2000, and will double again by 2020, and will almost triple by 2030. According to the report, 12 million people received cancer diagnosis during the current year, and more than seven million will die from the disease. In 2030, the new diagnoses will be between 20 and 26 million, and the number of deaths will reach 13 to 17 million.

"The contrast between the high-resource and low-resource countries is huge," said Peter Boyle, IARC director and co-editor of the report, introducing the document Dec. 9. "While cancer deaths rates are falling in the EU and the US and other high-resource countries, the great disparities which exist between groups at different levels of deprivation and access to care are masked. In low-resource settings, over 80 percent of cancers present at a stage when palliation is the only therapy which can be offered."

Meanwhile, 30 low-resource countries that don't have a single radiotherapy machine, and 29 African countries ban importation of opioid drugs for pain control. "Every terminal cancer patient has the basic human right to all aspects of supportive and palliative care and the absolute right to die a pain-free death with dignity," Boyle said at an Atlanta press conference sponsored by IARC, the American Cancer Society, the Susan G. Komen Foundation and the Lance Armstrong Foundation.

Boyle's term at IARC expired at the end of 2008.

"The rapid increase in the cancer burden represents a crisis for public health and health systems worldwide," Boyle said. "A major issue for many countries, even among high-resource countries, will be how to find sufficient funds to treat all cancer patients effectively and provide palliative, supportive and terminal care for the large numbers of cancers which will be diagnosed in the coming years."

Boyle said that focus should be on what he described as the "four pillars of Cancer Control."

"Prevent those cancers which can be prevented, treat those cancers that can be treated, cure those cancers that can be cured, and, provide palliation whenever palliation is required," he said.

One form of prevention, tobacco control, is feasible even for the poorest nations. "One third of cancers in high-resource countries are caused by tobacco smoking, which also causes a large proportion of deaths from other chronic disease including vascular disease and chronic pulmonary disease," Boyle said. "The worst of the tobacco epidemic in low-resource countries has yet to materialise. There is a 40-year temporal gap between big changes in tobacco prevalence in a population and the peak of the disease epidemic caused by this habit. Tobacco control is a major task for countries irrespective of their resource setting, and a number of measures have been shown to effectively reduce tobacco consumption, in particular taxation and smoking bans."

Other risk factors include alcohol consumption, excessive exposure to sunlight, lack of physical activity, overweight and obesity, some dietary factors, occupational exposures and chronic infection. "Effective prevention will reduce the risk of cancer and effective screening will allow many others to be diagnosed early and successfully treated for their disease," Boyle said.

In poor countries, common cancers are caused by chronic infections, many of which can now be treated. "In these circumstances, there are now prospects for prevention via vaccination for Hepatitis B (liver cancer) and Human Papillomavirus (cervix cancer), and treatment for Helicobacter pylori (stomach cancer)," Boyle said. "The major issue in the poorest countries is delivery of the prevention action at a price that is affordable for the countries health systems."

The three U.S. organizations involved in unveiling the report suggested a six-step program aimed at enhancing global cancer control:

—Making vaccines that prevent cancer causing infections more widely available to low-income nations, including specifically combating cervical cancer through Global Alliance for Vaccines and Immunizations (GAVI) efforts to make the HPV vaccine accessible and affordable;

—Committing to a comprehensive tobacco control approach in the U.S., which includes taking measures proven effective in reducing smoking rates and having Congress grant FDA authority to regulate tobacco;

—Ratifying immediately the Framework Convention on Tobacco Control (FCTC), the first ever global public health treaty that sets forth comprehensive measures to reduce health and economic impacts of tobacco;

—Supporting efforts of non-governmental organizations to build advocacy and resources, empower survivors and reduce suffering in low- to middle-income countries by working with governments, medical professionals and the corporate sector to enable individuals to adopt healthier behaviors;

—Promoting culturally sensitive risk reduction and education campaigns by leveraging our own successful U.S. efforts to help build capacity of nongovernmental organizations in other countries; and

—Investing in cancer research and expanding access to prevention and early detection measures in the U.S., with a specific focus on increasing federal funding of medical research.

"The report places great emphasis on where the needs are," said Bernard Levin, co-editor of the report and professor emeritus at M.D. Anderson Cancer Center. "Hopefully, it can be taken up by national and international organizations who want to try and make a difference."

The report will be available from WHO Press early next year. The email address is bookorders@who.int. Boyle said plans have been made to translate the report into French, Arabic, Chinese, and Russian.

Transition:

Corr, Of Tobacco-Free Kids, Nominated Deputy HHS Sec.

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to be made on the basis of science—period," he said.

Also, NIH needs to be strengthened, Daschle said. The Institutes have been "flat-funded in recent years, which has produced a 17 percent loss of buying power since 2003," he said. "There has been a sharp fall in the success rates for grant applicants, now as low as 10 percent for many NIH Institutes. It has also suffered from some instances of people putting politics before science.

"America has been an innovation leader, and part of its edge in the areas of biotech is attributed to NIH," Daschle said. "Countries around the world are trying to cut into that edge. I will work to strengthen NIH, with leadership that focuses on the dual objectives of addressing the health care challenges of our people and maintaining America's economic edge through innovation."

Daschle's prepared statement is available at http://help.senate.gov/Hearings/2009_01_08/Daschle.pdf.

The email circulated to HHS employees that included a list of acting agency officials didn't mention NCI, where Bush appointee John Niederhuber has submitted his pro forma resignation, but has said he would be "honored" to serve in the Obama administration (The Cancer Letter, Dec. 19, 2008).

NCI sources said there has been no word yet from Obama officials whether Niederhuber would be asked to stay.

In other transition news:

—**William Corr**, executive director of the Campaign for Tobacco-Free Kids, was nominated as deputy secretary of HHS. The nomination requires Senate confirmation. In the Clinton administration, Corr served as chief of staff to HHS Secretary Donna Shalala, and prior to that, he was chief counsel and policy director for then-Senate Majority Leader Daschle (D-S.D.). He also has served as staff to Rep. Henry Waxman (D-Calif.).

—**John Holdren**, a Harvard physicist, is Obama's pick for science advisor and director of the White House Office of Science and Technology Policy. He also will serve as co-chairman of the President's Council of Advisors on Science and Technology.

Harold Varmus, president of Memorial Sloan-Kettering Cancer Center, and **Eric Lander**, director of the Broad Institute, will serve as the two outside co-chairmen of PCAST.

— **Frank Torti**, FDA chief scientist and principal deputy commissioner, will serve as acting commissioner. Torti, who joined FDA last fall, was director of the Comprehensive Cancer Center at Wake Forest University and chairman of cancer biology.

Addressing a recent report critical of FDA's oversight of medical devices, Andrew von Eschenbach, in his last news conference as FDA commissioner Jan. 13, likened the agency to a cancer patient.

"It is a great shock and surprise when someone says you have cancer," he said, according to The New York Times. "The truth of the matter is that process has been going on for a long time before it became apparent in that particular way."

Earlier in 2008, von Eschenbach declared that FDA had been "eminently successful up to this period of time."

—**Raynard Kington**, acting NIH director, will continue to serve in that post. Kington served as deputy director under Elias Zerhouni, who stepped down as NIH director last fall.

—**William Gimson III**, chief operating officer of CDC, will serve as acting director when Julie Gerberding steps down. Gerberding has served as CDC director since July 2002.

—**Sanjay Gupta**, CNN medical correspondent, has been reported to be Obama's first choice for Surgeon General. Gupta is an assistant professor at Emory University Medical School and associate chief of neurosurgery at Atlanta's Grady Memorial Hospital.

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