THE CANCER LETTER

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Trial Shows Benefit For Old Drugs, Device, For Ovarian Cancer; Will Practice Change?

By Kirsten Boyd Goldberg

NCI's clinical announcement earlier this month encouraging intraperitoneal administration of chemotherapy to some women with stage III ovarian cancer was the culmination of several decades of academic and government-funded research on a therapy that has no obvious sponsor—no drug or device company—to market it.

The therapy involves inserting a catheter into the abdomen to bathe the peritoneal cavity with two standard anticancer drugs, cisplatin and paclitaxel, following surgical removal of ovarian tumors. IP chemotherapy allows

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In Brief:

NCI Research Deputy Richard Alexander To Move To University of Maryland

H. RICHARD ALEXANDER JR., deputy director of the NCI Center for Cancer Research since 2003, was named associate chairman for clinical research at the University of Maryland Department of Surgery. As a surgical oncologist, he also will treat patients at the University of Maryland Marlene and Stewart Greenebaum Cancer Center.

Alexander is recognized for developing innovative techniques to treat patients with advanced cancers of the gastrointestinal tract, especially isolated hepatic perfusion, a way to circulate high doses of chemotherapy directly into the liver to treat patients with inoperable cancer. He is also known for his expertise in endocrine disorders.

Alexander has been at NCI for 16 years. He became chief of the surgical metabolism section in 1995. A graduate of the University of Colorado, Alexander received his medical degree from Georgetown University School of Medicine. He completed his residency in general surgery at the National Naval Medical Center in Bethesda and did a fellowship in surgical oncology at Memorial Sloan-Kettering Cancer Center.

"Dr. Alexander is an internationally known surgical oncologist who is widely recognized for pioneering treatments for patients with advanced liver and pancreatic cancer and melanoma," said **Stephen Bartlett**, chairman and professor of surgery at the University of Maryland School of Medicine and chief of surgery at the University of Maryland Medical Center. "He will lead our clinical research program to new levels of success." Greenebaum Cancer Center Director **Kevin Cullen** called Alexander "one of the most outstanding surgical oncologists in the country… [and] a world-class researcher."

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NCI Clinical Alert On IP Chemo Recommends Specialty Care

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higher doses and more frequent drug administration, and appears to be more effective in killing cancer cells in the peritoneal cavity, where ovarian cancer is likely to spread or recur first.

Cisplatin and paclitaxel, both initially developed by Bristol-Myers Squibb, are available in generic form. The catheters are standard equipment, the same that are used in renal dialysis.

"The way it usually is, there's a drug and there's a company that's going to talk about it, but we don't have anything here like that," said Maurie Markman, vice president for clinical research at University of Texas M.D. Anderson Cancer Center, who has been involved in clinical trials of the therapy since the 1980s.

"There's nothing in this for anyone, except the patient," Markman said. "That's why NCI, appropriately, expressed interest. There needs to be a big effort to get people to know about it, because the push is going to come from patients. There's no external source of interest like a drug company."

The therapy wasn't widely known outside gynecologic oncology until Jan. 5, when NCI issued a clinical announcement about the results of a phase III trial published in that day's New England Journal of Medicine comparing IP chemotherapy for ovarian cancer with standard intravenous chemotherapy. NCI makes such statements when results represent a major clinical benefit to patients.

Standard treatment for women with stage III ovarian cancer has been surgical removal of the tumor followed by six to eight courses of IV chemotherapy given every three weeks. Platinum drugs, such as cisplatin or carboplatin, and a taxane drug, such as paclitaxel are used.

The NCI clinical announcement recommends that women with advanced ovarian cancer who undergo effective surgical debulking receive a combination of IV and IP chemotherapy.

"IP therapy is not a new treatment approach, but it has not been widely accepted as the gold standard for women with ovarian cancer," said medical oncologist Deborah Armstrong, an associate professor at Johns Hopkins Kimmel Cancer Center who led the study. "There has been a prejudice against IP therapy in ovarian cancer, because it's an old idea, it requires skill and experience for the surgery and for the chemotherapy, and it's more complicated than IV chemotherapy. But now we have firm data showing that we should use a combination of IP and IV chemotherapy in most women with advanced ovarian cancer who have had successful surgery to remove the bulk of their tumor."

The study, conducted by the Gynecologic Oncology Group, enrolled 429 women with stage III ovarian cancer who were given chemotherapy following the successful surgical removal of tumors. It compared two treatment regimens: IV paclitaxel followed by IV cisplatin, to IV paclitaxel followed by IP cisplatin and the subsequent administration of IP paclitaxel.

The 205 women who received the IP chemotherapy had a median survival time that was 16 months longer than women who received only IV chemotherapy, even though most of the women in the IP group received fewer than the six planned treatments. Complications associated with the abdominal catheter were the main reason only 86 of the women completed all six IP treatments.

Severe or life-threatening (grade 3 and 4) pain, fatigue, hematologic, gastrointestinal, metabolic, and neurologic toxic effects were more common in the IP group than in the IV group, the researchers wrote. The toxicity could be attributed to the higher dose of cisplatin that the IP group received, but it could also be due to the IP paclitaxel, they wrote. "Careful monitoring of toxicity and the use of contemporary supportive care measures might improve the tolerability of the regimen we used," they wrote.

There were nine treatment-related deaths—four in the IV group and five in the IP group.

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Quality of life was significantly worse in the IP group, but one year after treatment, women in both groups reported the same quality of life.

"Randomized, multicenter clinical trials, including this most recent study, clearly show the value of IP chemotherapy—an extended life for women with advanced ovarian cancer," said GOG Chairman Philip DiSaia.

Patients Urged to Find Specialists

Armstrong said some clinicians might be deterred from offering IP chemotherapy due to cost and lack of familiarity with the procedure. The catheter placement means that the patient has to be in a hospital bed, with nursing care to monitor for complications and toxicity. "We haven't done a cost analysis, but we expect IP therapy to be more expensive than intravenous—more drug and more staff time," she said.

Also, patients with adhesions or surgical complications, poor kidney function, and those who have had the left side of their colon removed during surgery are not ideal candidates for IP therapy. It also is not clear whether the procedure has any benefit for recurrent disease or patients with large amounts of residual disease after surgery.

NCI's clinical announcement encouraged physicians to refer potentially eligible patients to specialists or centers that will offer the therapy. NCI said six professional societies and advocacy groups supported the statement.

NCI posted a list of institutions with expertise in management of ovarian cancer, including surgery and IP chemotherapy, at http://ctep.cancer.gov/highlights/ovarian.html.

"The fact that this is shown to be better doesn't mean that every oncologist in America should be prepared to do it," Markman said. "Many doctors refer leukemia patients to other centers, because they have a particular expertise. In an office where an oncologist sees one patient like this every other year, it may not be reasonable for them to maintain the supplies and training that goes into this."

In that case, physicians should "tell the patient about the option and help them find a place where they could do it," Markman said.

"Gynecologic oncologists are the most prepared to do this," Markman said. "They have larger practices, and they have done this for a long time. These randomized trials were done all around the country. It's the same drugs—we've been giving platinum for 25 years—and the same hydration, and the same anti-nausea drugs. There's nothing different—you put it in the catheter. It's pretty darn simple.

"I don't want to say medical oncologists can't do it, because they can, but it's more likely that a gynecologic oncologist will have had experience doing it, so that if a woman is operated on by gynecologic oncologist, then already she's there," Markman said. "But if she wasn't operated on by a gynecologic oncologist, she might ask if there is one in the area who can do this."

Initial Surgery Called Critical Step

A different problem occurs with the initial surgery, experts said. Fewer than half of women with ovarian cancer in the U.S. seek a gynecologic oncologist for their surgery, despite research showing better outcomes for this group.

"The first and most important step is good surgery," said Robert Bristow, director of the Johns Hopkins Ovarian Cancer Center. "If you don't start with a surgeon specializing in gynecologic oncology who can effectively remove most of the tumor, then intraperitoneal chemotherapy may not work."

According to the NCI statement, "Effective surgical debulking is critical to long-term survival for ovarian cancer. Women undergoing surgery for presumed ovarian cancer, therefore, should undergo surgery by a gynecologic oncologist or a surgical team with expertise in the staging and cytoreduction of ovarian cancer. After primary surgery, women with optimally-debulked FIGO stage III ovarian cancer should be counseled about the clinical benefit associated with combined IV and IP administration of chemotherapy. Based on the most recent trials, strong consideration should be given to a regimen containing IP cisplatin (100 mg/m^2) and a taxane, whether given by an IV only or IV plus IP."

The Society of Gynecologic Oncologists said IP chemotherapy should be considered only in women who have undergone optimal cytoreductive surgery with residual tumor nodules less than 1 cm in diameter. "In this regard, studies have shown that gynecologic oncologists are more likely to perform optimal debulking of ovarian cancer than other surgeons," SGO said in a statement. "The NCI recommendation that IP chemotherapy be considered only for patients who are optimally debulked further highlights the importance of referral of women with known or suspected ovarian cancer to a gynecologic oncologist or other physician with special expertise and training in ovarian cancer cytoreductive surgery."

The SGO statement was cautious about the potential benefit for patients. "Although there is good evidence

that IP chemotherapy increases median survival, it remains unclear whether this translates into higher cure rates," the society said. "In addition, there is presently no consensus regarding what constitutes the 'standard' IP chemotherapy regimen. Furthermore, the intensity and toxicity of IP chemotherapy generally is higher than that of IV chemotherapy, and IP chemotherapy may be poorly tolerated by patients who do not have an excellent performance status.

"In view of these issues, the decision whether or not to use IP chemotherapy should be decided on a case-by-case basis by each patient and her physician," SGO said.

From Mathematical Modeling To Clinical Trials

IP chemotherapy was first considered 40 years ago for colon cancer, when chemotherapy drugs became available.

The concept was revisited in the late 1970s by a group at NCI, led by a mathematician, Robert Dedrick, who has since retired. "He was a brilliant man who looked at a lot of data, and he knew about pharmacology of drugs, and said that if you put certain drugs in the abdominal cavity, you would get tremendous exposure," Markman said. "It was all theoretical."

In a sense, it's a story about the importance of academic and government-supported research, Markman said. "Dr. Dedrick was even more basic than a basic scientist, not even working with tissue. He was working with numbers," he said. "But he had all this information that was out there in kidney dialysis, and he knew a lot about the pharmacology, and started playing with these numbers, and he knew about the metabolism of the drugs in the liver. He said, 'Gee, you would get really increased exposure.' The investigators picked that up on that, and we are where we are today."

The approach was tested in animals, then in phase I trials to confirm the pharmacology, and then progressed to phase II and III studies. However, in the 1980s and 1990s, the benefits were overshadowed by the promise of new drugs such as paclitaxel and carboplatin.

The results of seven trials assessing the administration of IP chemotherapy for first-line treatment of ovarian cancer have become available over about the past 10 years, the NCI clinical announcement said.

Besides GOG, other cooperative groups participated in the trials. "We are pleased to know that our research helped confirm the value of peritoneal chemotherapy in improving survival for women with advanced ovarian cancer," said Laurence Baker, chairman of the Southwest Oncology Group, which led two trials of the therapy. "This validates the Southwest Oncology Group mission of conducting clinical trials that measurably improve the outcome of patients with cancer."

Including the recent GOG study, two other randomized trials show a benefit for patients, Markman said.

"It's a very nice story, from a true concept, with some interesting modeling ideas, based on what was known about pharmacology, that you could expose tumor to very high concentrations," Markman said. "We learned that the drugs penetrate to a very limited extent, we learned all that stuff as we did the early work, then trials were designed—and guess what? It worked."

The next steps will be to try to figure out how to make it better. "Maybe we can come up with better catheters," Markman said. "Maybe we can work on ways to get more drug in. And, of course, other drugs. What about some of the newer drugs? These are future research questions."

The text of the NCI clinical announcement and further information on IP chemotherapy administration is available at www.gog.org.

FDA News:

Package Insert Revised, Seeks To Preempt Liability Lawsuits

By Paul Goldberg

A new FDA rule revises the format of package inserts for prescription drugs and seeks to make it more difficult for patients to file product liability suits against pharmaceutical companies in state courts.

The labeling changes—the first in 25 years—reorganize information contained in the labels and mandate a new graphical format for the usually lengthy documents. The new format includes a half-page section called "Highlights," which provides information on risks and benefits of the agents.

Also mandated is inclusion of a table of contents, the date of initial approval, and a toll-free number and Web address to encourage reporting of adverse events. The labeling requirements will initially apply to new approvals and indications approved over the past five years, the agency said.

In a press conference Jan. 18, administration officials described the new format as an effort to prevent medical errors.

Legal experts said it is unclear how effective the new FDA rule will be in preempting product liability suits in state courts. The preemption provision is contained in a preamble to the new rule, and was not

contained in its draft version, which was published in the Federal Register in December 2000.

"FDA believes that under existing preemption principles, FDA approval of labeling… whether it be in the old or new format, preempts conflicting or contrary State law," the final rule states. "Indeed, the Department of Justice, on behalf of FDA, has filed a number of amicus briefs making this very point.…

"Under the [Food, Drug and Cosmetic Act] and FDA regulations, the agency makes approval decisions based not on an abstract estimation of its safety and effectiveness, but rather on a comprehensive scientific evaluation of the product's risks and benefits under the conditions of use prescribed, recommended, or suggested in the labeling, FDA considers not only complex clinical issues related to the use of the product in study populations, but also important and practical public health issues pertaining to the use of the product in day-to-day clinical practice, such as the nature of the disease or condition for which the product will be indicated, and the need for risk management measures to help assure in clinical practice that the product maintains its favorable benefit-risk balance."

Lawyers experts expect that the provision will be extensively challenged, and that judges will interpret it in a variety of ways.

The provision is consistent with FDA Acting Commissioner Andrew von Eschenbach's view of the drug development process, which emerged during his four years as NCI director.

Three years ago, top officials at NCI floated a plan that proposed changes in product liability measures that would apply to development of agents for prevention of cancer based on their impact on biomarkers (The Cancer Letter, May 30, 2003). Product liability suits have since slowed down development of agents like Vioxx and Celebrex for cancer prevention after data from NCI-sponsored randomized trials demonstrated that these drugs were associated with significant toxicities (The Cancer Letter, Jan. 7, 2005).

Speaking as FDA acting commissioner, von Eschenbach said the changes in the label format will benefit patients and doctors. "The new label design makes it easier for doctors to get access to important information about drug safety and benefits, and this in turn will help them have more meaningful discussions with their patients," he said in a statement. "This redesigned label is a big step in our commitment to giving health professionals the tools and information they need to optimize their clinical practice and choose among a growing number of effective treatments to make more personalized prescribing decisions for their patients."

FDA said that approximately 300,000 preventable adverse events occur in US hospitals every year, and the new format will make this information more accessible.

"It's a typical abuse by the Bush Administration—take a regulation to improve the information that doctors and patients receive about prescription drugs and turn it into a protection against liability for the drug industry," said Sen. Edward Kennedy (D-Mass.)

Trial lawyers protested the new provision. "The fact that the drug industry can get the FDA to rewrite the rules so that CEOs can escape accountability for putting dangerous and deadly drugs on the market is the scariest example yet of how much control these big corporations have over our political process," said Ken Suggs, president of the Association of Trial Lawyers of America.

"Eliminating the rights of individuals to hold negligent drug companies accountable puts patients in even more danger than they already are in from drug company executives that put profits before safety and an FDA that is beholden to the drug companies it is supposed to regulate," Suggs said in a statement.

The final rule is posted at www.fda.gov/cder/regulatory/physLabel/default.htm.

Capitol Hill:

Senate Panel Investigating Pharma "Educational Grants"

By Paul Goldberg

The Senate Committee on Finance is ramping up its investigation of the pharmaceutical companies' use of "educational grants."

In letters sent to pharmaceutical companies last week, the committee said it is investigating whether such grants are being used to promote products and demanded internal information.

The request for materials seeks to determine whether marketing personnel is involved in decisions to award educational grants to professional societies and patient advocacy groups.

"It's hard to see how you could call some of these grants 'educational,' " Sen. Chuck Grassley (R-Iowa), chairman of the committee, said in a statement. "Some groups have learned that their very survival depends on drug company money. In that case, it seems pretty obvious that their independence may be compromised. We need to look at just how beholden these groups are

to the money they're getting."

Sen. Max Baucus (D-Montana), ranking member of the committee said educational grants should be "awarded for legitimate educational activities and not for marketing purposes."

"In the best cases, drug companies use these grants to give back to communities and to make sure that Americans have all the information they need about products that can keep us healthy," Baucus said in a statement. "But if drug companies are crossing the line with these grants, and influencing providers to make treatment decisions they might not otherwise make, that's a problem and we're going to tackle that."

The committee started the investigation last June, and last week's letters to drug companies indicate that the investigation continues. According to the committee, requests for information were sent out to Johnson & Johnson, Pfizer, GlaxoSmithKline, Merck & Co., Inc., AstraZeneca Pharmaceuticals LP, Bristol-Myers Squibb Co., Novartis Pharmaceuticals Corporation, Amgen Inc., Wyeth Pharmaceuticals, Eli Lilly & Co., SanofiAventis, Eisai Inc., Boehringer Ingelheim Pharmaceuticals Inc., Schering-Plough Corp., Hoffman-LaRoche Inc., Forest Pharmaceuticals Inc., Abbott Laboratories, Genentech Inc., BiogenIdec Inc., Genzyme Corp., Chiron Corp., Serono Inc., and TAP Pharmaceutical Products Inc.

The letters, dated Jan. 9, request that information be provided by Feb. 6.

An excerpted text of the letters follows:

After reviewing information provided by drug manufacturers in response to the committee's initial request and from other sources, the committee seeks additional information about certain practices.

Most notably, as chairman and ranking member of the committee we seek to better understand the role(s) of sales and marketing personnel in initiating and/or evaluating grants, and the use of grants to provide funding to professional societies or associations and patient advocacy organizations.

With respect to the role of sales and marketing personnel in the grant approval process, we are concerned that sales and marketing personnel may influence the awarding of grants in a way that favors those individuals or organizations that are known to advocate use of specific product(s). With respect to the use of educational grants to fund professional and patient advocacy organizations, we are concerned that such organizations, many of which develop treatment or practice guidelines, may come to rely on such funding to an extent that may compromise their independence. The committee is also interested in funding provided to academic institutions or state agencies to support the development of practice guidelines or treatment algorithms.

The information provided by some companies in response to the committee's first letter inquiring about educational grants and other inquiries about the underwriting of efforts to promote the use of drugs raises additional questions. We recognize that much of this information represents past practices and might not continue under current policies and procedures.

In reviewing documentation submitted in response to our initial request, our committee staff found that many manufacturers have modified their grant policies and procedures in response to the PhRMA Code, issued in 2002, and the Department of Health and Human Services Office of Inspector General's *OIG Compliance Program Guidance for Pharmaceutical Manufacturers*, issued in 2003.

However, it appears that many manufacturers', sales and/or marketing personnel still have a role in originating or evaluating grant requests, and, consequently, the potential for abuse remains. In addition, it appears that most manufacturers continue to provide funding to professional societies and patient advocacy organizations, but the information received by the committee shows that only one drug manufacturer considers the portion of funding they provide to such organizations when evaluating grant requests.

Accordingly, we remain concerned about both the direct and indirect influence that manufacturers may have on such organizations. Accordingly, … we request that your company provide the following information to the committee:

1. Please describe in detail the role(s) of marketing and/or sales personnel in receiving, processing and/or evaluating grants.

2. Please provide a list of all grants or other payments made to medical/physician/professional organizations or "medical specialty societies" in fiscal years 2003 and 2004. The list should identify the name of the organization receiving the grant or other payment, the amount of the grant or other payment, the date of the grant or other payment, the purpose of the grant or other payment and a description of the activity funded. In addition, please indicate whether the grant or other payment supported, either directly or indirectly, the following:

—the development and/or dissemination of journal articles and/or other published material;

—the development and/or dissemination of practice or treatment guidelines; and/or

—the development, dissemination and/or implementation of medication algorithms.

3. For all grants identified in Question 2 as supporting published materials, practice or treatment guidelines and medication algorithms, either directly or indirectly, please provide the title, journal of publication (if applicable), date of publication, and any method of dissemination other than publication in a peer-reviewed journal.

4. Please provide a list of all grants or other payments made to patient education or advocacy organizations in fiscal years 2003 and 2004. The list should identify the name of the organization receiving the grant or other payment, the amount of the grant or other payment, the purpose of the grant or other payment, and a description of the activity funded.

5. For each organization that received a grant identified in response to Questions 2 and 4, please indicate whether your company determined and/or considered the total amount of support your company provided to the organization as a percentage of its total funding.

6. Please provide a list of all grants or other payments made to academic institutions or state agencies and/or their agents or employees in fiscal years 2003 or 2004 that supported, either directly or indirectly, the following:

—the development and/or dissemination of journal articles and/or other published material;

—the development and/or dissemination of practice and/or treatment guidelines; and/or

—the development, dissemination and/or implementation of medication algorithms.

The list should identify the following: the name of the institution, agency, or individual receiving the grant or other payment; the amount of the grant or other payment; the date of the grant or other payment; the title of the article, guideline, or treatment algorithm; the journal of publication (if applicable); the date of publication, and any method of dissemination other than publication in a peer-reviewed journal.

Funding Opportunities:

Foundation Offers Grants

Two-year Investigator Grant for up to $200,000 ($100,000/yr) plus 15 percent overhead. Deadline: April 3.

Two-year Program Grant for up to $600,000 ($300,000/yr) plus 15 percent overhead. Preliminary Application Deadline: March 1.

The Samuel Waxman Cancer Research Foundation seeks to develop Scientific Programs in the form of an "Institution Without Walls." These programs span multiple institutions and disciplines and identify the best set of investigators to attack specific problems in cancer. Researchers would focus on collaboration, communication, and translational cancer research. The foundation will accept one individual grant application and/or one program application from each institution. Each application should include a cover letter indicating how the candidate was chosen. Funding will begin July 1.

Guidelines, applications and information are available at www.waxmancancer.org. Inquiries and applications: applications@waxman.cancer.org.

RFA Available

RFA-RM-06-006: Training for a New Interdisciplinary Research Workforce

Letter of Intent Receipt Date: Feb. 14. Application Receipt Date: Apr. 7.

The initiative promotes training approaches using existing, emerging, or underdeveloped interdisciplinary sciences. The goal of training interdisciplinarians is to ensure that each researcher will be able to speak the language of the interdiscipline, understand the basis of each discipline component, be able to train others in the interdiscipline, and emerge as leaders in the development of interdisciplinary science. Programs may target undergraduate, graduate, postdoctoral, or faculty-level training. The funding opportunity will use the R90 and T90 award mechanisms. The RFA is available at http://cri.nci.nih.gov/4abst.cfm?initiativeparfa_id=3316.

Inquiries: Allison Chausmer, achausme@nida.nih.gov.

RFP Available

RFP No. N01-CO-57035-48: NCI Best Case Series Program: Prospective Research Projects

NCI Office of Cancer Complementary and Alternative Medicine BSC Program is interested in alternative approaches to cancer treatment and promotes collaborative activities between Complementary & Alternative Medicine practitioners and more traditional cancer researchers. Eligible topics are alternative cancer therapies for which patient documentation is available and for which the intervention is available for prospective investigation.

Proposals should be prospective research projects justified on the basis of results from the findings of a completed review of a case submission to the NCI BCS Program and any contract awarded will result in a completed research project within two years.

The announcement is available at the Web site of the Office of Acquisitions, NCI, at: http://rcb.cancer.gov/rcb-internet/appl/rfp/published_rfps.jsp.

Inquiries: John Manouelian, 301-435-3813; manouelj@mail.nih.gov.

Other Funding Notices

NOT-CA-05-022: Rapid Access to Intervention Development.

Receipt Due Dates: Feb. 1 and Aug. 1.

NCI invites project proposals for the RAID program that will make available to the preclinical development contract resources of the NCI Developmental Therapeutics Program. RAID is not a grant program.

The goal of RAID is the rapid movement of novel molecules and concepts from the laboratory to the clinic for proof-of-principle clinical trials. Possible tasks may include production, bulk supply, good manufacturing process manufacturing, formulation, and toxicology. Suitable agents for RAID will include small molecules, biologics, or vaccines. The notice is available at http://grants1.nih.gov/grants/guide/notice-files/NOT-CA-05-022.html.

Inquiries: 301-496-8720; raid@dtpax2.ncifcrf.gov.

NOT-CA-06-005: Rapid Access to Intervention Development. The notice is available at http://grants1.nih.gov/grants/guide/notice-files/NOT-CA-06-005.html.

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