THE CANCER LETTER

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PO Box 9905 Washington DC 20016 Telephone 202-362-1809

ESA Risk Mitigation Strategy Requires Training, Patient Consent, Documentation

By Paul Goldberg

FDA has approved a "risk evaluation and mitigation strategy" for erythopoiesis-stimulating agents for chemotherapy-related anemia.

The measures, known under the acronym REMS and mandated two years ago by the FDA Oncologic Drugs Advisory Committee, require additional training and certification for healthcare providers as well as distribution of a "medication guide" for patients who may be receiving these agents.

ESAs, which for years have been a mainstay of the practice of oncology and a significant source of revenues for oncologists, have been shown in eight studies to be associated with increased risk of strokes, heart attacks,

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FDA News:

FDA Approved More Than 50 New Indications For Cancer In 32 Months, Analysis Finds

FDA's Office of Oncology Drug Products approved more than 50 new indications for the use of oncology and hematology drugs and biologics between July 2005, when the office began reviewing marketing applications, and the end of 2007, according to a new agency study.

During the time period, the office reviewed 60 applications from companies seeking approval to treat people with 30 different types of cancer, including breast, lung, colon, kidney, head and neck and several forms of blood cancer.

The Office of Oncology Drug Products, part of the Center for Drug Evaluation and Research, took action on 58 of the applications, approving 53 new cancer indications. Five applications were not approved, and two applications were withdrawn before any regulatory action was taken. These approved applications included indications for 18 new drugs that had not been previously approved and 35 additional indications for already approved drugs.

"Our reviews during this period focused on approving new or existing treatments based on treatment effect, patient safety, and the treatment's risk-benefit profile," said Rajeshwari Sridhara, lead author of the FDA analysis and an acting division director in CDER's Office of Biostatistics. "We also considered the patient populations in need of additional treatment

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Two Years After ODAC Mandate FDA Unveils ESA Risk Strategy

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and tumor progression.

Through the risk management program, Amgen must ensure that health care professionals who treat patients with cancer do the following:

• Register and maintain enrollment in the ESA program. This measure stops short of maintaining a central registry of patients receiving ESAs.

• Complete training on the use ESAs in patients with cancer.

• Enroll in the ESA risk management program every three years.

• Discuss the risks, benefits, and FDA-approved uses of ESAs with cancer patients before beginning a course of ESA treatment. Patients would be informed that using these drugs is associated with increased risk of stroke, heart attack, heart failure, blood clots, tumor progression, and death.

• Health care providers would have to document this discussion with a written acknowledgement from the patient. Information would be provided at the initiation of treatment and whenever treatment is dispensed.

Amgen, which manufactures the cancer ESAs Aranesp and Procrit, is also required to oversee and monitor health care professionals and hospitals that administer ESAs in oncology. Procrit is produced by Amgen, but marketed in oncology by Johnson & Johnson.

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Editor: Paul Goldberg

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ESAs are also approved for the treatment of anemia that may occur as a result of kidney failure, from the drug AZT, which can be used for the treatment of HIV infection, and for the treatment of anemia among certain patients undergoing surgery.

The risk management program, called APPRISE, which stands for "Assisting Providers and Cancer Patients with Risk Information for the Safe Use of ESAs," would be initiated within 45 days after FDA approval.

The program was approved on Feb. 16, and REMS certification for physicians and hospitals would begin on March 25.

"Amgen will be monitoring through the ESA APPRISE center the compliance with enrollment and certification," Patricia Keegan, director of the FDA Division of Biologic Oncology Products, said in a telephone press conference Feb. 16.

It will take up to a year from the point of initiating the ESA APPRISE program for physicians and hospitals to enroll, Keegan said. "We are not encouraging that they wait that year," she said. "What we are suggesting is that there will be some time for people to become familiar and to register during that initial period.

"At the end of the year, Amgen will begin to take action with regard to restricting distribution to any oncologist that is not registered," Keegan said.

Under the program, Amgen would be required to submit assessments that document the progress made in getting physicians and hospitals enrolled in the program. "FDA will review those assessments and can then initiate further discussions with Amgen if there appear to be any difficulties in meeting the goal," Keegan said.

ODAC had been consulted on the ESA safety problem four times since 2004. At a meeting in March 2008, ODAC recommended that the risks be addressed through patient consent (The Cancer Letter, March 21, 2008). On April 22, 2008, FDA sent a letter directing Amgen to develop an ESA risk management program.

Asked by a reporter why the strategy took so long to develop, FDA officials pointed to unusual characteristics of oncology practice and the manner in which the drug is distributed.

"This was a unique situation," Keegan said. "We have not yet faced a REMS that applied to multiple agents. We have not yet faced a REMS where these elements to assure safe use were applied to only one of the approved indications. So this was breaking new ground for FDA and the sponsor in order to come up with the plan that would be able to be flexible enough to deal with the clinical practice of oncology, where it's

estimated that less than five percent of patients receive their drug from a retail pharmacy. Many of the REMS are focused around the retail pharmacy as the point of restricted distribution. In this sense, it's really quite groundbreaking."

Richard Pazdur, director of the FDA Office of Oncology Drug Products, said the agency didn't want to interfere with the practice of medicine. "It isn't as straightforward as one would expect, and one has to walk through all the different scenarios to ensure that this program accomplishes our goal and minimizes any burden it has in prescribing ESAs," Pazdur said.

"We understand that the requirements of the safe use program will create new responsibilities for busy healthcare providers," Pazdur said. "It will require additional time for training, record-keeping, and other tasks related to complying with the program's requirements. However, we are not doing this to make things more difficult for healthcare providers. We are doing this to make absolutely certain that patients are fully informed of the risks related to the use of these drugs before they begin treatment and throughout their treatment regimen."

Pazdur said the safety requirement is based on findings in multiple studies that demonstrated that ESAs caused tumors to grow faster or resulted in earlier deaths.

"The risk pertaining to patients with cancer is specific, and the data underscoring that risk are strong," Pazdur said. "Eight studies involving various types of cancer demonstrated a risk of stimulating growth of tumors and/or decreasing the survival time in patients receiving cancer treatment.

"For patients receiving cancer treatment that has the potential for cure, ESA's risk may undermine this therapeutic goal," Pazdur said. "For patients whose cancer treatment is palliative, the risk-benefit may be different.

"In this case, the risk-benefit balance is a delicate one, and by requiring additional education on the part of the healthcare providers and ensuring that patients have all the drug risk information we can help patients make the best possible choice, given their individual situation," Pazdur said.

Aranesp sales have been declining for two years since the streak of bad news that began in January 2008. During fiscal 2009, Aranesp sales declined by 24 percent from the previous year, Amgen said in its regulatory filings.

"The ESA REMS represents our continued commitment to patient education and safety," Roger Perlmutter, executive vice president of research and development at Amgen, said in a statement. "This program supports a thoughtful dialogue between healthcare providers and patients when considering ESA treatment."

Amgen and the J&J unit Centocor Ortho Biotech Products said they will distribute a Dear Healthcare Provider letter about the program, its requirements and consequences for non-enrollment. Also, information will be posted on the program's website, www.esa-apprise.com.

FDA News:

Agency Analysis: 50 Approvals Since Oncology Office Formed

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options, existing treatments, and whether this was a new molecular entity."

The agency's retrospective analysis appears in the Feb. 24 issue of the Journal of the National Cancer Institute. The journal article is available at http://jnci.oxfordjournals.org.

Approval data from July 1, 2005 through Dec. 31, 2007, were reviewed by the authors for this analysis. This review was started after the formation of the Office of Oncology Drug Products and the implementation in 2007 of the Food and Drug Administration Amendments Act. The review included indications for both conventional oncology drugs and biological oncology products reviewed in CDER. It did not include products reviewed in other FDA centers.

"The FDA used a variety of trial designs and endpoints in approving these applications. In addition, we implemented recent regulatory initiatives including accelerated approval and priority reviews to expedite the approval of these indications," said Richard Pazdur, director of the Office of Oncology Drug Products, and one of the review's co-authors.

The accelerated approval process allows for earlier approval of drugs to treat serious diseases with an unmet medical need and is based on a surrogate endpoint, a laboratory measurement or physical sign that is used in clinical trials as an indirect measurement of clinical benefit. Under an accelerated approval, the FDA approves the drug on the condition that the drug manufacturer conducts further studies to evaluate the drug's actual clinical benefit. Priority reviews are conducted within six months, whereas other reviews are usually reviewed in 10 months.

Other highlights from the cancer drug approvals review include:

•New treatments were approved for six of the seven most deadly forms of cancer in the United States (lung, colon, breast, ovarian, cervical and pancreatic).

•35 of the approvals were existing products seeking new treatment indications.

•New molecular entities represented 18, or 34 percent, of the 53 approvals.

•Approvals included treatments for pediatric patients, supportive care indications aimed at improving the side effects of cancer therapies, and treatment options for rare diseases.

•Three new treatments were approved for advanced kidney cancer.

•Nine drugs received accelerated approval, a regulatory mechanism allowing the FDA to approve a drug with subsequent studies performed after approval to demonstrate an effect on survival or other clinically meaningful endpoints.

•Twenty five percent of the indications approved were based on improvement in overall survival or improvement in both progression-free survival and overall survival.

Rituxan Approved For Chronic Lymphocytic Leukemia

FDA approved Rituxan (rituximab) on Feb. 18 to treat certain patients with chronic lymphocytic leukemia.

Rituxan is intended for patients with CLL who are beginning chemotherapy for the first time and for those who have not responded to other cancer drugs for CLL. Rituxan is administered with two other chemotherapy drugs, fludarabine and cyclophosphamide.

"Rituxan is the third drug approved for the treatment of CLL since 2008 and underscores FDA's commitment to expediting the development and approval of drugs for patients with serious and life-threatening diseases," said Richard Pazdur, director, Office of Oncology Drug Products in the FDA's Center for Drug Evaluation and Research.

FDA approved Arzerra (ofatumumab) in October 2009 for patients whose cancer is no longer being controlled by other forms of chemotherapy and Treanda (bendamustine) in March 2008 for patients with CLL who had not received prior treatment.

Rituxan is a monoclonal antibody. It is manufactured through biotechnology methods rather than by the human body's own immune system. The drug binds to the surface of cancer cells, making it easier for the patient's immune system to attack the cancer cell as if it were a foreign pathogen.

The safety and effectiveness of Rituxan was evaluated in two studies that measured progression-free survival, defined as the time a patient in the study lived without the cancer progressing.

In one study of 817 patients who had not received any prior chemotherapy, progression-free survival was eight months longer for those receiving Rituxan plus chemotherapy than for those who received chemotherapy alone. In another study of 522 persons whose cancer had progressed following other chemotherapy drugs, progression-free survival was five months longer for those who received Rituxan plus chemotherapy.

The FDA analyzed the data on patients 70 years of age and older who had received Rituxan and found no evidence that adding the drug to chemotherapy benefitted elderly patients compared to receiving chemotherapy alone. However, there was also no evidence that Rituxan was harmful to elderly patients.

Rituxan carries a Boxed Warning for infusion reactions, which can occur during infusion or within 24 hours afterwards. Some 59 percent of patients treated with Rituxan for CLL experienced an infusion reaction that resembled an allergic reaction (e.g., hives, low blood pressure, chills, fever, and nausea).

A decrease in infection-fighting, normal white blood cells was also commonly observed in patients enrolled in the Rituxan clinical trials.

Other Boxed Warnings for Rituxan include rashes and sores in the skin and mouth; progressive multifocal leukoencephalopathy (PML), a brain infection that is generally fatal; and tumor lysis syndrome, which results from the death of a large number of tumor cells in a short period of time. When the tumor cells are killed by the drug, they release toxins into the bloodstream that can cause acute kidney injury and increase the levels of potassium and phosphate in the blood.

Rituxan is manufactured by San Francisco based-Genentech, a member of the Roche Group.

Medicare:

Reimbursement Change Meant To Save Money Costs More

Increased Medicare payments to physicians for outpatient surgeries for bladder cancer have led to a dramatic rise in the number of these procedures being performed and an overall increase in cost to the healthcare system, according to a study published online Feb. 8 in CANCER, a journal of the American Cancer Society.

The findings indicate that some Medicare policies aimed at decreasing costs may instead be contributing to an increase in healthcare expenditures, the article said. Because bladder cancer is the most expensive cancer to treat, its management places a significant economic burden on the U.S. healthcare system, which costs two to four times that of healthcare systems in any other industrialized nation.

In an attempt to reduce costs, in 2005 Medicare increased physician reimbursement for office-based endoscopic bladder procedures, such as biopsies. Moving these procedures from the more expensive inpatient hospital setting to the presumably less expensive outpatient office setting could cut costs provided that they are performed for the same indications, are equally efficacious, and are tolerable to patients.

The reimbursement change was expected to alter physician incentives, leading to increased use of outpatient endoscopic surgery, a decline in hospital-based endoscopic surgery and, consequently, a reduction in healthcare-related costs.

To evaluate this hypothesis, Micah Hemani, and Samir Taneja, of the Division of Urologic Oncology at the New York University Langone Medical Center, assessed treatment patterns in their practice before and after the Medicare change in physician reimbursement.

The investigators found that the number of outpatient bladder surgeries doubled after Medicare reimbursements rose, but the number of hospital-based surgeries did not significantly decline. As a result, there was a 50% increase in overall Medicare costs.

While there was an increase in patient referrals for outpatient surgeries, it was not sufficient enough to account for the increased use of these procedures. There was, however, a rise in the redundant use of outpatient surgery on patients who also underwent hospital-based surgery for the same condition. Also, while the number of outpatient procedures increased, the likelihood that a procedure would lead to a bladder cancer diagnosis declined.

"We believe these trends are disturbing as they may reflect both diagnostic and therapeutic over-utilization of office-based endoscopic bladder surgery," the authors wrote.

The reasons for this surge in use of outpatient procedures are unknown but might include improvements in office-based equipment for surgery, improved physician comfort and skill with these operations, and the incentive of receiving increased financial reimbursement. Whatever the cause, these findings suggest that Medicare financial incentives for the outpatient treatment of bladder cancer may actually increase overall costs without improving care.

Hemani noted that the study's results illustrate a need for clinical guidelines for these office-based surgeries, as well as a need for policy measures that ensure accountability for physicians who perform them.

"Given the ongoing healthcare debate in Congress regarding reforming the current system, one wonders if many of the changes currently being proposed in Washington might not have similar effects to what we are seeing in this one isolated example," said David Penson, of Vanderbilt University in Nashville, who was not involved with the study but wrote an accompanying editorial. "Sometimes, policies have the exact opposite effect of what was intended."

Obituary:

Former FDA Commissioner Arthur Hull Hayes Jr., 76

ARTHUR HULL HAYES JR., who led FDA during the Tylenol crisis of 1982, died Feb. 11 from complications caused by a chronic illness. He was 76.

Hayes, a professor of medicine and pharmacology and director of clinical pharmacology at Pennsylvania State University, was appointed by President Ronald Reagan as FDA commissioner in 1981. He directed FDA's response to the Tylenol tampering cases the following year. He left FDA in 1983.

Hayes was born in Highland Park, Mich., and received an A.B. in philosophy from Santa Clara University in 1955. He went to Oxford University as a Rhodes Scholar, receiving a degree in philosophy, politics, and economics in 1957. He received an M.D. from Cornell University Medical School in 1964, and then served in the U.S. Army Medical Corps from 1965 to 1967. He worked as an assistant professor of medicine and pharmacology at Cornell before moving to Penn State.

After leaving FDA, Hayes served as provost and dean at New York Medical College. In 1986, he was named president of E.M. Pharmaceuticals, a division of Merck. Five years later, he founded a consulting firm, from which he retired in 2005.

He is survived by his wife, Barbara Anne of Oxford, CT; three children; two sisters; a brother; and eight grandchildren.

In the Cancer Centers:

CINJ, Princeton To Collaborate On Cancer Research, Training

THE CANCER INSTITUTE OF NEW JERSEY formally welcomed Princeton University as a scientific collaborator. CINJ, an NCI-designated comprehensive cancer center, operates under a "consortium cancer center" matrix allowing for formal scientific and academic collaboration with other entities. Rutgers has been part of this relationship since CINJ first opened in 1993, allowing for Rutgers scientists to work alongside CINJ's physician scientists in CINJ laboratories and vice-versa. The partnership with Princeton University will allow for the same.

Princeton research efforts are housed within numerous departments, institutes and centers, including the Lewis-Sigler Institute for Integrative Genomics and the Princeton Physical Sciences-Oncology Center, which was recently established with a $15.2 million grant from NCI to explore how cancer evolves under stress.

CINJ Director **Robert DiPaola** said the formal partnership will allow both institutions to take advantage of shared resources such as equipment, databases and personnel, and would create joint training opportunities for post-doctoral students. He also notes the addition of Princeton research members to the consortium will further strengthen the entity as a research leader in the region, thus helping attract additional state and federal funding.

MARGARET TEMPERO received the 2010 Claude Jacquillat Award Feb. 3 at the International Congress of Anti-Cancer Therapy, for her research in pancreatic cancer and her leadership in the development of translational research in this disease. Tempero is deputy director and director of research programs at the UCSF Helen Diller Family Comprehensive Cancer Center.

EMORY UNIVERSITY School of Medicine said **Tammie Quest**, associate professor in the Department of Emergency Medicine, with a secondary appointment in the Division of Geriatric Medicine and Gerontology, was named interim director of the Emory Center for Palliative Care. She serves as the chief of the Section of Palliative Medicine at the Atlanta VA Medical Center, and is the former director of the Georgia Cancer Center for Excellence, Palliative Care Oncology Program, Grady Health System. She is the fellowship program director for the Emory University School of Medicine program in hospice and palliative medicine.

NIH News:

Raynard Kington Named President Of Grinnell College

RAYNARD KINGTON, NIH principal deputy director since 2003, who served as acting NIH director from November 2008 until August 2009, has accepted the position of president of Grinnell College, starting in July.

Kington joined NIH in 2000 as director of the NIH Office of Behavioral and Social Sciences Research, then served as acting director of the National Institute on Alcohol Abuse and Alcoholism.

"I am delighted for him and his family, and Grinnell College is fortunate indeed to have recruited a new president of such outstanding capabilities and character," NIH Director Francis Collins said in a statement. "I must say, however, that I have a lump in my throat imagining Raynard leaving the NIH, where he has made so many outstanding and long-lasting contributions. Personally, I could not ask for a better deputy director, who has guided me on so many critical issues since last August."

As acting NIH director, Kington led the effort to allocate $10.4 billion of Recovery Act money, and implement President Obama's Executive Order on human embryonic stem cell research.

NIH Grant Application Changes

NIH implemented newly restructured and shortened grant application forms on Jan. 25.

These changes are the result of the Enhancing Peer Review Initiative, which began in 2007 with an evaluation of the current peer review system. In June 2008, the evaluation resulted in an implementation plan.

Recommendations that have been phased in include: changes in new and early investigator policies; one resubmission limit; enhanced review criteria; and a new scoring system. The final major recommendations

that were put in place in January include shorter page limits and restructured forms.

NIH is also restructuring the applications by aligning the structure and content with the new enhanced peer review criteria released in December 2008. Changes include a Research Strategy Section that includes subsections addressing significance, approach, and innovations; an enhanced biographical sketch including a personal statement.

Applications for due dates on or after Jan. 25 require the new forms. Applicants should go to the reissued Program Announcements and updated Funding Opportunity Announcements to download new applications and instructions. Applicants must be careful to select the correct SF424 (R&R) electronic forms or PHS398 paper forms, if applicable. The changes apply to all competing applications: new, renewal, resubmission, and revision.

Funding Opportunities:

NIH Accepts Weather Delays

NIH said it will allow organizations affected by extensive winter storms some leniency in grant application deadlines.

Electronic and paper applications submitted late because of weather problems must include a cover letter noting the reasons for the delay, NIH said in its Guide for Grants and Contracts. The delay should not exceed the time period that an applicant organization was closed. The statement is available at http://grants.nih.gov/grants/guide/notice-files/NOT-OD-10-016.html.

OS Recovery Act Limited Competition: Accelerating Adoption of Comparative Effectiveness Research Results by Providers and Patients (R18) - Announcing Additional Funds Availability and Clarifying Eligible Institutions/Organizations. http://grants.nih.gov/grants/guide/notice-files/NOT-AE-10-001.html

ARRA OS Recovery Act 2009 Limited Competition: Comparative Effectiveness Delivery System Evaluation Grants (R01) http://grants.nih.gov/grants/guide/rfa-files/RFA-HS-10-012.html

Comprehensive Partnerships to Reduce Cancer Health Disparities (Limited Competition U54) (RFA-CA-10-503)

Modification of RFA-CA-10-007 to Increase Applicants Flexibility for Proposing the Number of Clinical Trials to be Accomplished in the Funding Period (NOT-CA-10-016)

Change in Application Receipt Date for PAR-10-003 Specialized Programs of Research Excellence (SPOREs) in Human Cancer for Years 2010, 2011 and 2012 (P50) (NOT-CA-10-017)

Notice of Intent to Establish a New NIH Common Fund Program: Library of Integrated Network-Based Cellular Signatures (LINCS) (NOT-RM-10-002)

Scientific Meetings for Creating Interdisciplinary Research Teams (R13) (PA-10-106)

Philanthropy:

Komen Provides $1 Million For NCI-Latin America Study

Susan G. Komen for the Cure is providing $1 million to help fund the development of breast cancer research programs in Latin America, in a partnership led by the NCI Office of Latin American Cancer Program Development.

The program will support the development of programs for cancer research, clinical trials, training programs, technology, and capacity building in five Latin American countries.

"Breast cancer is a leading cause of death in Latinas here in the United States and around the world, and requires a large-scale effort to address and overcome," said Nancy Brinker, founder and CEO of Komen for the Cure. "This landmark collaboration between Komen, NCI, and five Latin American countries will help us get to answers about genetics, environment and social issues that contribute to breast cancer deaths in Latinas."

The research will be conducted in Argentina, Brazil, Chile, Mexico and Uruguay. Brinker and NCI Director John Niederhuber signed an agreement for funding Feb. 18. This follows the signing of bilateral agreements among the five countries and the NCI last fall.

The countries will link their research efforts through the cancer Biomedical Informatics Grid, an information network that allows researchers to share data and knowledge. This is the first major multi-country research effort specifically aimed at women in Latin American countries.

The first step is building the information database to identify breast cancer patterns in Latin women. Then the project will develop strategies for improved breast cancer detection, management and treatment in Latin America, enhanced research training and developing a clinical research infrastructure for the future.

Breast cancer is the leading cause of cancer death among Latina women in the U.S. and cancer incidence in Latin American countries is rising.

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