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Talking Back: FDA Faces Two Challenges Over Avastin & Prostate Cancer Prevention

By Paul Goldberg

Talking back to FDA's oncology division used to be considered counterproductive, like fighting city hall.

But in 2011, something seems to have changed. The agency's decisions in cancer are being vigorously challenged by complex commercial, academic and political constituencies.

The challenges stem from two separate cases:

- For the first time, FDA has revved up the machinery for removing an indication under the accelerated approval process, and the company that holds the indication slated for removal—Genentech—is fighting back. On Jan. 18, Genentech requested a hearing to challenge the decision to withdraw the

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In the Cancer Centers:

Gray Moves to OHSU Knight Cancer Institute; Roswell Park Gets \$4.3mil for Disparity Program

JOE GRAY joined the Oregon Health & Science University Knight Cancer Institute and was named chair that institution's Department of Biomedical Engineering. His job is to establish the programs of the Center for Spatial Systems Biomedicine, where he serves as director. The center will use a combination of physics, biomedical engineering, chemistry and biology to study how cancer cells grow.

Gray began moving his research team to OHSU from the Lawrence Berkeley National Laboratory starting Jan. 1.

Gray said the multidisciplinary center would develop the teams and infrastructure to create next-generation cell "assembly manuals" that would describe how molecular aberrations in cells function as a system and how function is modulated by anatomic context.

"Research in the past several decades has been focused on understanding the molecular components of cancer," he said. "The next phase of research will determine how the parts work together. Once you know how the parts work together in individual patients and in anatomic context, it will be easier to understand how to develop more effective and durable treatments."

Gray's contributions to science include inventions of aspects of flow cytometry. Also, he was a key participant in the development of the fluorescence in situ hybridization (FISH) and comparative genomics hybridization (CGH) tests. Gray is a former professor at the Departments of

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Genentech Files Document To Dispute Avastin Decision

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metastatic breast cancer indication of the drug Avastin (bevacizumab).

• A group of doctors is openly disagreeing with recommendations by the Oncologic Drugs Advisory Committee to bar agents Proscar (finasteride) and Avodart (dutasteride) from being used in prevention of prostate cancer (The Cancer Letter, Dec. 3, 2010). Though no decision has been made, the agency is expected to deny this indication.

The guideline-writing committee operated jointly by the American Society of Clinical Oncology and the American Urologic Association is considering convening a meeting to review the ODAC recommendation, sources said.

If the committee is allowed to convene and if it upholds its existing guideline, which recommends these drugs as an option, this would amount to supporting an off-label use that directly contradicts a negative determination by the agency, observers said.

"It is not a certainty" that the panel will change its recommendation to remove chemoprevention with these drugs, called 5-alpha reductase inhibitors, said Paul Schellhammer, co-chairman of the panel that formulated the most recent ASCO-AUA recommendation and past president of AUA. "There will be extensive evaluation and reevaluation by the panel that constructed the current joint ASCO and AUA guideline to determine

the extent—if any—it needs to be modified as a result of ODAC recommendations and the expected FDA decision."

Schellhammer, a professor at Eastern Virginia Medical School and medical director of the Virginia Prostate Center, said he was not speaking for the guideline committee or the organizations that support it.

William McGivney, CEO of the National Comprehensive Cancer Network, said that to the best of his knowledge, until recently his group never recommended a specific drug or biologic for an indication that went directly against a specific negative recommendation from FDA.

This changed in October, when NCCN decided to keep the Avastin breast cancer indication in its breast guideline despite a negative vote from ODAC (The Cancer Letter, Oct. 22, 2010).

"Our docs, who basically see breast cancer patients day and night, look at the data and come up with their recommendation about bevacizumab or any other drug," McGivney said. "In the case that we have right now, obviously, our guys looked at the data, interpreted it, and stuck with their original recommendation about use in combination with paclitaxel."

Remember Robert Fildes?

More often than not, challenges to FDA actions in oncology are mounted by small biotech firms that have nothing to lose after the demise of their single product.

Even then, companies rely on surrogates in the academia and patient groups, or surreptitiously make rounds on Capitol Hill to try to trigger an investigation, or make on-background calls to a reporter.

A search for exceptions takes one far—very far—back: to July 31, 1990. On that day, the FDA Biological Response Modifiers Advisory Committee said no to an application for interleukin-2 for the renal cancer indication. Robert Fildes, president and CEO of Cetus Inc., the drug's sponsor, held a press conference at which he blasted FDA officials.

The agency had erased data tapes, some statements of the medical reviewer amounted to "red herrings," and both the agency and its advisors had taken an impractical approach by "playing pure science," Fildes raged (The Cancer Letter/Cancer Economics, August 1990). Soon after returning to Emeryville, Calif., cigar-chomping Fildes found himself out of work.

More typical is the position taken by Bristol-Myers Squibb when this publication focused on the FDA decision to disregard the unanimous recommendation by ODAC and deny the BMS application for the colorectal

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cancer drug UFT.

Academics, including the ODAC chairman and several committee members, found this appalling. Also, a Congressional committee started to ask questions (The Cancer Letter, July 21, 2000).

Fearing revenge from the agency, BMS responded by trying to make the investigation go away, and launched its own internal probe to try to determine how the story leaked out.

Genentech Takes Aggressive Stance

Today's challenges to FDA are particularly noteworthy because all the drugs in question are on the market, and the controversy stems from supplemental New Drug Applications.

Genentech's case is untested. There is no way to predict how the agency's mechanism for withdrawing accelerated approval will function and how effective the company's political strategy will be.

Before Genentech's troubles began, the drug was generating about \$1 billion in sales in the breast cancer indication.

According to this week's filing, the drug's growth has stopped, and the proportion of new prescriptions has decreased from 59 percent prior to the ODAC decision to 35 percent in the fourth quarter of 2010.

"This trajectory shows that clinicians and patients have modified their treatment choices based on the uncertainty surrounding the ODAC decision and FDA actions, but despite this uncertainty (and an agreed-upon marketing moratorium), a substantial core level of use continues," the company said in the filing. "This use pattern indicates that clinicians and patients continue to view Avastin as an important option for certain patients and, in particular, are not finding that the drug has an unacceptable toxicity profile."

The document is posted at <http://www.gene.com/gene/news/news-events/avastin/>.

Unlike Genentech, GlaxoSmithKline, the sponsor of Avodart, is unlikely to adopt an aggressive strategy.

At the ODAC meeting, the agency and committee members noted that Avodart and Proscar are associated with higher incidence of high-grade tumors, which could jeopardize Avodart's labeled indication as a treatment of benign prostatic hyperplasia.

Proscar, which has gone off-patent, is approved for BPH as well as for hair loss. Its sponsor, Merck, came to the meeting because it was invited to show up by the agency. Its presentation was based on the results of the NCI-sponsored Prostate Cancer Prevention Trial.

Merck wasn't asking for a new indication. It sought

to add information about chemoprevention to the label.

However, physicians who support the indication say that the ODAC vote was wrongheaded.

"I think the issue of chemoprevention is extremely important, and should go hand-in-hand with early screening, and my opinion and advice to patients is to consider it as part of a risk-reduction strategy," Schellhammer said to The Cancer Letter.

Laurence Baker, chairman of Southwest Oncology Group, which conducted the Prostate Cancer Prevention Trial of finasteride, slammed FDA even before the agency announced its decision.

"We believe the PCPT trial results and the subsequent analyses done on PCPT data have demonstrated for the first time a proof of principle that a drug can reduce the risk of prostate cancer by a significant amount," Baker, an oncologist at the University of Michigan, said in a SWOG newsletter. "That the drug's prevention benefit was greater in men with lower Gleason scores does not detract from the fact that prostate cancer risk reduction for the thousands of men who took part in PCPT was real and was significant."

"I've had a radical prostatectomy, and if given a choice would have much preferred to take a pill every day and not have cancer to deal with," Baker said. "If you are given a choice of not having prostate cancer or having prostate cancer, which would you choose, regardless of whether it would lengthen your life?"

"If the FDA's ODAC believed finasteride and dutasteride actually increased high-Gleason score prostate cancer, why did they then fail to remove the drugs from the market for a large population of men with BPH, some of whom certainly harbor prostate cancer?"

The SWOG newsletter article containing Baker's comments is posted at <http://swog.org/visitors/newsletters/2010/12/index.asp?A=spotlight>

FDA officials said they are, in fact, reviewing the labels of 5-alpha reductase inhibitors in light of information presented at ODAC.

"We are considering the recent advisory committee discussion in the context of the risks and benefits of these drugs for their approved uses for BPH and hair loss," said Karen Mahoney, the agency spokesman. "We cannot say more at this point since our review is ongoing."

GSK spokesman Rob Perry said the company has confidence in the data supporting the BPH indication.

"Our position coming away from the ODAC was disappointment for the prospects of developing a way to help physicians and patients reduce the risk of prostate cancer," Perry said. "But, on the flip side, we have not

changed confidence in position around Avodart as a treatment for BPH.”

The company expects to receive a letter from FDA next week.

If professional societies part ways with FDA and encourage an off-label use of 5-alpha reductase inhibitors for prostate cancer prevention, the company will discourage such use, Perry said.

“We do not promote our medications for off-label use,” he said. “We will discourage and not condone this. That is a GSK policy that has been repeatedly affirmed, and enforced, and reemphasized, and reemphasized, and reemphasized.”

Genentech Wants to Perform Another Trial

In its filing to FDA, Genentech asks the agency to extend its accelerated approval for Avastin while the company conducts a new confirmatory trial in which Avastin would be administered with weekly paclitaxel.

In 2008, the agency approved the use of Avastin in combination with weekly paclitaxel, based on the Eastern Cooperative Oncology Group’s trial E2100. However, confirmatory trials, led by Genentech’s parent company Roche, sought to expand the indication to other combinations.

In one of these trials—AVADO—the drug was used with Taxotere (docetaxel) every three weeks. In another trial—RIBBON 1—it was used with a taxane/anthracycline combination in one cohort and with capecitabine in another. RIBBON 1 had no weekly taxane arm.

This difference between regimens used with Avastin could, at least theoretically, affect the outcome of studies. Breast cancer experts point to a puzzling finding: data show that weekly paclitaxel appears to produce greater efficacy than once-every-three-week docetaxel.

The Roche confirmatory trials produced improvements in progression-free survival, but not of the magnitude FDA regarded as sufficient to warrant approval (The Cancer Letter, July 23, Sept. 3, 2010).

The agency has started the process to remove the breast cancer indication, (The Cancer Letter, Dec. 17, 2010). The company’s filing this week signifies that it intends to fight the withdrawal and initiate the hearings.

The Genentech filing reads:

In this particular case, the current dataset supports maintaining accelerated approval of Avastin in combination with paclitaxel.

In 2008, FDA determined that the data from E2100 met the standard for accelerated approval. AVADO

and RIBBON1, which combined Avastin with other commonly used chemotherapy partners, were positive studies that met their primary PFS endpoints and confirmed a positive effect on tumor control.

The lower magnitude of effect on median PFS in AVADO and RIBBON1 is an observation consistent with clinical experience that some chemotherapy agents (and their dose and schedule) yield different levels of clinical benefit.

Genentech viewed AVADO and RIBBON1 as confirming a clinical benefit of Avastin in MBC. ODAC and FDA came to a contrary conclusion based on the lower magnitude of effect on median PFS in these trials.

However, even if FDA views AVADO and RIBBON1 as failing to confirm the clinical benefit of Avastin in MBC for purposes of conversion to full approval, Genentech respectfully submits that this view does not justify the opposite conclusion of withdrawal.

AVADO and RIBBON1 do not negate the clinical benefit that FDA recognized when it granted accelerated approval based on the substantial PFS effect observed with Avastin plus paclitaxel. Rather, the data from these additional studies are consistent with an unforeseen limitation in the designs of the confirmatory trials—namely, the degree of difference in the magnitude of clinical benefit when Avastin is used in combination with paclitaxel versus with other chemotherapies.

As such, the potential exists to characterize further the benefit observed in E2100 with an additional study specifically testing the combination of Avastin with weekly paclitaxel. Thus, the totality of the current data continues to meet the letter and spirit of the accelerated approval provisions of the FDCA and FDA’s regulations.

The data justify the continued availability of Avastin plus paclitaxel to address the immediate needs of women with MBC, who can derive clinical benefit while an additional study is conducted to characterize this clinical benefit more fully.

The Paclitaxel Hypothesis

The company would like the new confirmatory trials to focus on the hypothesis that mimics the E2100 study.

The filing reads:

While multiple hypotheses can be generated for why a differential effect would be observed with distinct chemotherapy partners, the current lead hypothesis is that chemotherapies that provide for prolonged combined exposure with Avastin may yield the strongest treatment effects.

In E2100, the combination with weekly paclitaxel

allowed for prolonged exposure to both the cytotoxic and anti-angiogenic agents, as evidenced by a median chemotherapy duration of 7.3 months for Avastin plus paclitaxel, compared with a median chemotherapy duration of 5.1 months for paclitaxel alone.

In contrast, treatment durations with combinations with docetaxel and anthracyclines are limited by the cumulative toxicities of the chemotherapy agents. Thus, the protocols for AVADO and RIBBON1 included limitations on exposure to docetaxel (maximum of nine 3-week cycles) and anthracyclines (maximum of eight 3-week cycles), corresponding to a maximum of only 27 or 24 weeks of combined treatment, respectively.

In retrospect, these restrictions related to the tolerability of alternate chemotherapies represent limitations of their study designs in serving as confirmatory trials for E2100. Although the differential effect observed in E2100, AVADO, and RIBBON1 is not well understood, the different magnitude of benefit observed in these studies (including differences within RIBBON1 for capecitabine compared with the other chemotherapies) establishes a real and credible hypothesis that warrant further investigation for a differential effect for Avastin with paclitaxel.

Given the data, FDA goes too far in its Decision Memorandum when it dismisses the hypothesis that paclitaxel is a preferred partner with Avastin because the rationale for a “unique interaction between Avastin and paclitaxel ... has not been substantiated.”

Genentech should not be required to have proven that paclitaxel is a preferred chemotherapy partner in order to maintain accelerated approval; rather, Genentech should have the opportunity to conduct a further study while accelerated approval is maintained.

Genentech's Proposed Trial

The filing contains the following description of a confirmatory trial Genentech proposed:

Following the 20 July 2010 ODAC meeting, Genentech submitted a proposal to FDA for a confirmatory study of Avastin: a double-blind, randomized, multicenter, phase III study designed to characterize further and confirm the efficacy and safety of Avastin in combination with paclitaxel, as shown by E2100.

PFS would be the primary efficacy endpoint, and OS, 1-year survival, and response rate would be secondary efficacy endpoints. This study would include a biomarker component to identify patients who may be more likely to derive a more substantial benefit from Avastin.

As presented by the investigators at the December 2010 San Antonio Breast Cancer Symposium, recent data analyses from AVADO suggest that plasma VEGF-A may be a potential predictive marker for Avastin activity.

Patients with high levels of VEGF-A had a PFS hazard ratio of 0.49 (standard dose), whereas patients with low levels of VEGF-A had PFS hazard ratio of 0.86. This finding suggests that patients with high levels of VEGF-A may be more likely to derive a more substantial benefit from Avastin.

The relevance of VEGF-A is scientifically plausible given Avastin's inhibitory activity on the biologic actions of VEGF. A biomarker program has been an integral part of Genentech's research on Avastin.

A large number of markers (over 10,000 in preclinical and over 100 in clinical studies) have been studied in a variety of tumor types (including MBC, pancreatic cancer, gastric cancer, colorectal cancer, lung cancer, and brain cancer) for prognostic and predictive biomarkers.

These biomarkers include plasma and tumor markers, circulating endothelial and progenitor cells, imaging, and genetic polymorphisms. In phase III trials of Avastin, using a first-generation VEGF assay, VEGF was a strong prognostic—but not predictive—marker for Avastin's efficacy.

However, using a second-generation VEGF test, VEGF at baseline demonstrated a potential predictive effect in MBC and pancreatic cancer for patients with samples available.

NCCN vs. ODAC

In the filing, Genentech argues that members of the advisory committee that voted 12 to 1 to remove Avastin's breast cancer indication were not as qualified to evaluate the drug as members of the NCCN panel who voted in favor of the indication.

The document reads:

In October 2010, the NCCN affirmed its recommendation for use of Avastin in combination with paclitaxel, after having reviewed the same data that were considered by the 20 July 2010 ODAC.

The NCCN Guidelines are developed and updated on the basis of an evidence-based process, with explicit review of scientific evidence by multidisciplinary panels of expert physicians. The contrasting conclusions of ODAC and the NCCN may stem from the differing composition of these groups and their distinct directives.

ODAC is a heterogeneous panel of advisors consisting of oncologists with different specialty

expertise, statisticians and consumer and patient advocates. ODAC is asked to advise FDA on a broad spectrum of oncologic drugs across the spectrum of cancer treatment, which is increasingly specialized. Only two of the 13 ODAC members at the 20 July 2010 ODAC meeting were breast cancer oncologists (one breast oncologist and one women's cancer specialist), and both were temporary voting members recalled from the 2007 ODAC meeting on E2100 by FDA.

A key component of the evaluation of Avastin as a treatment option is understanding how patients and physicians can weigh the safety information as part of their benefit-risk assessment for Avastin in MBC. Hence, a richer perspective of clinicians on ODAC familiar with the use of Avastin in the clinic would have been valuable to inform discussion of the use of Avastin in MBC.

By contrast, the NCCN Breast Cancer panel comprises clinicians and oncology researchers specializing exclusively in breast cancer from the NCCN Member Institutions. Thus, the continued inclusion of Avastin with paclitaxel in the NCCN Guidelines reflects the recommendations of breast cancer clinicians focusing on treatment experiences and clinical realities, whereas ODAC's recommendation reflects the views of a heterogeneous advisory panel including a more generalist group of oncologists, statisticians, and others evaluating a body of clinical study data as presented by FDA and the sponsor.

Individuals with both expertise in breast oncology and experience with the clinical use of Avastin are best positioned to evaluate the benefit-risk balance of Avastin in MBC. Respectfully, we submit these qualities are more clearly reflected in the composition of the NCCN Breast Cancer Guidelines panel than in ODAC.

The Process

Though the 1992 law that created the accelerated approval mechanism allows for removing indications, no drug has ever gone through this process. Accelerated approval drugs have been removed from the market in the past, but via less cumbersome means.

- In 2005, the drug Etyol (amifostine), marketed by MedImmune, lost one of its indications, reducing the cumulative renal toxicity from cisplatin in non-small cell lung cancer. The drug is still marketed for its other indications. The indication was withdrawn voluntarily because of emergence of better treatment options for non-small cell lung cancer.

- Last year, Mylotarg (gemtuzumab ozogamicin) was withdrawn by the sponsor, Pfizer Inc., because three

studies failed to demonstrate its efficacy in the approved indication, acute myeloid leukemia. Technically, this, too, is not a revocation of an indication.

- Iressa (gefitinib), sponsored by AstraZeneca, was placed in a restricted access program that barred physicians from prescribing it to new patients. This action, in 2005, was caused by failure of confirmatory trials to demonstrate a survival advantage. Withdrawal procedures are spelled out in 21 CFR Subpart H 314.530.

Here is how the process works:

- The director of the FDA Center for Drug Evaluation and Research writes a letter containing a "notice of an opportunity for a hearing" on the center's proposal to withdraw the approval of an application. The letter contains the reasons for the action. This is what has happened with the Proamatine application last month.

- The sponsor then has 15 days of receipt of the notice, the applicant waives the opportunity for a hearing. If the sponsor requests a hearing, the agency announces the hearing in the Federal Register. The sponsor then has 30 days of receipt of the notice of opportunity for a hearing to submit the data and information which would form the basis of the hearing.

- "An advisory committee" would be present at the hearing, the regulations state. However, it's not clear whether this would be the same committee that would have been consulted on approval. The committee will be asked to review the issues involved and to provide advice and recommendations to the FDA commissioner.

- The presiding officer, the advisory committee members, up to three representatives of the applicant, and up to three representatives of the center may question any person during presentations. No other person attending the hearing may question a person making a presentation. The presiding officer may, as a matter of discretion, permit questions to be submitted to the presiding officer for response by a person making a presentation.

- The commissioner's decision would constitute final agency action from which the applicant may petition for judicial review.

ASCO Will Not Take Position on Avastin

Though many oncologists will likely take part in debates over Avastin, ASCO intends to steer clear of the emerging debate, said society president George Sledge.

"ASCO will be making no public comments, pro or con, regarding Genentech's appeal of the FDA's decision on Avastin in breast cancer," Sledge said to The Cancer Letter. "The society's position, not specific to this particular drug or indication, is that the process

of drug approval should be an open and transparent one.

"As the FDA has followed a standard review process that included an open presentation at ODAC, we do not feel that it is appropriate for us to take a pro or con decision on the outcome of that process," said Sledge, the Ballve-Lantero Professor of Oncology and Professor of Medicine and Pathology at Indiana University Simon Cancer Center. "We do have concerns regarding what represent acceptable endpoints in clinical trials of cancer drugs, and encourage the FDA to work with the oncology community to examine the process by which such endpoints are determined, and to make the endpoints as clear as possible so that the drug development community can generate advances in an efficient and collaborative fashion."

ASCO has no guideline on the use of Avastin.

Sledge said he was not aware of emerging challenges to the agency's expected action on Proscar and Avodart. However, Schellhammer said the AUA-ASCO guideline committee review is being organized and would be convened "sooner rather than later."

In the Cancer Centers: **Indiana Receives \$3.4 Million For Palliative Care Research**

(Continued from page 1)

Laboratory Medicine and Radiation Oncology at the University of California, San Francisco, and director of the Division of Life Sciences at Lawrence Berkeley National Laboratory. He served as principal investigator of an NCI Breast Cancer SPORE for almost 15 years and currently is PI of NCI Center for Cancer Systems Biology award, a DOD Innovator Project on early cancer detection, and co-principal investigator of a Stand Up to Cancer Dream Team.

Gray will be joined by several research staff members from Lawrence Berkeley National Laboratory including Paul Spellman, a genome scientist and key participant in The Cancer Genome Atlas project, who will contribute to the new center and serve as a faculty member in the Department of Molecular & Medical Genetics.

Gray will also recruit six new faculty in aspects of multiscale imaging science, reporter chemistry and cell and tissue engineering who will hold primary appointments in either basic or clinical departments.

The recruitment of Gray and his team is part of the OHSU Knight Cancer Institute's strategy to use the \$100 million gift from Nike Chairman Phil Knight and his wife, Penny.

At OHSU, Gray also holds the Gordon Moore Endowed Chair in Biomedical Engineering.

In a related development, the OHSU Knight Cancer Institute recruited **Marilyn Owens** to serve as chief operating officer of the OHSU Knight Diagnostic Laboratories, which will offer tests that create a detailed genetic map of a patient's tumor.

Owens is the former senior vice president of operations for Caris Life Science and has held senior positions at IMPATH Inc., Genzyme Genetics and the Nichols Institute.

ROSWELL PARK CANCER INSTITUTE received a five-year, \$4.3 million grant from the NCI Center to Reduce Cancer Health Disparities that will enable the cancer center and five community health partners to launch a multi-pronged effort to reduce cancer health disparities in three counties of Western New York.

Deborah Erwin, director of cancer health disparities research at RPCI, and **Willie Underwood**, of the Department of Urology, are principal co-investigators on the U54 grant. A total of 23 Community Network Programs across the country received U54 funding.

The grant will create the Western New York Cancer Coalition to Reduce Disparities, uniting the efforts of RPCI, the Community Health Center of Buffalo and Niagara Falls, the P² Collaborative, the Health Network in Chautauqua County, the University at Buffalo and the Niagara Falls Memorial Medical Center. The project will encompass:

- Programs to reduce cancer disparities through improved access to screening, early detection, and treatment;
- Efforts to recruit more Latino volunteers to contribute biological samples and lifestyle information for the Data Bank and BioRepository, a large database maintained at RPCI that supports research at RPCI and other institutions;
- Innovative tobacco-cessation techniques using voice-recognition technology; and
- Training and career development.

Martin Mahoney, of the Departments of Health Behavior and Medicine at RPCI will help direct another component of the program, to "promote the delivery of smoking-cessation services within both community-based and primary-care medical settings." The project will create a registry of smokers and utilize automated voice recognition so primary care physicians in the community can record automated-delivery phone

messages to their patients who smoke, to reinforce the importance of quitting and to provide advice and encouragement.

INDIANA UNIVERSITY MELVIN AND BREN SIMON CANCER CENTER received a \$3.4 million grant from the **Walther Cancer Foundation** to promote research and education of palliative care.

The grant, which creates the Walther Program in Palliative Care Research and Education, will help clinicians, researchers and educators at the IU Simon Cancer Center learn to integrate palliative care into conventional cancer care and to provide the highest quality of life for patients and their families.

The Walther Program in Palliative Care Research and Education will build upon the expertise of clinicians and researchers currently engaged in palliative care at the IU Simon Cancer Center to design, test and implement evidence-based palliative care practices.

Physicians will design and test simulated patient-physician conversations about end-of-life care to enhance the quality of communication and decision-making near the end of life.

The Palliative Care Research and Education program also will provide for healthcare provider education in palliative care; testing novel interventions; developing and testing innovative programs to address unmet needs of family caregivers; assessing the impact of palliative care on the health care system; cross-disciplinary collaboration with health care providers; public advocacy; and resources to recruit a nationally-renowned investigator.

SANOFI-AVENTIS and **Oxford University** entered into an agreement to conduct multi-phase oncology clinical and translational research with INDOX, India's leading academic oncology network.

Through this partnership, sanofi-aventis will have access to the expertise and experience of India's top oncologists and scientists to conduct clinical research to the highest internationally recognized ethical standards.

Under the agreement, sanofi-aventis will provide financial support to Oxford University to manage the INDOX network of eight leading cancer-research centers across India.

The university will provide training and support to investigators and research coordinators to help ensure that each center has the capacity, expertise and infrastructure to perform early- through late-stage and post-marketing clinical trials according to ICH/GCP standards.

The network was established in 2005 as a partnership between the Institute of Cancer Medicine at the University of Oxford and India's top eight comprehensive cancer centers.

Funding Opportunities:

J&J Seeks Award Nominations; LLS Issues RFP on Research

JOHNSON & JOHNSON opened a call for nominations for the 2011 **Dr. Paul Janssen Award for Biomedical Research**, which recognizes individuals whose scientific research has made, or has the potential to make, significant transformational contributions toward the improvement of human health.

Nominations are available at www.pauljanssenaward.com and will be accepted until Feb. 15, 2011, for consideration by an independent selection committee of world renowned scientists. The winner or winners will receive a \$100,000 cash prize.

The 2010 award was presented to **Anthony Fauci**, director of the National Institute of Allergy and Infectious Diseases and **Erik De Clercq**, chairman of the Department of Microbiology and Immunology of the Medical School at the Catholic University of Leuven.

LEUKEMIA AND LYMPHOMA SOCIETY has identified four specific areas of need, and is soliciting grant applications from scientists and physicians who are working on these difficult problems.

The RFPs focus on researchers working in the following areas:

- Identification and characterization of the leukemic stem cell in acute myeloid leukemia and myelodysplastic syndrome and the identification of potential targeted therapies.
- Novel therapeutic strategies for non-cutaneous T-cell lymphoproliferative disorders.
- Development of therapeutic strategies for the high-risk myeloma patient.
- Mechanisms underlying long term and late effects resulting from cancer treatment and the development measures to significantly reduce or prevent these toxicities

Applications responsive to these RFPs should be submitted under LLS's Translational Research Program, a program designed to help accelerate the movement of promising discoveries from the lab to the clinic.

A detailed description of the LLS Translational Research Program and application instructions are available at <https://proposalcentral.altum.com/>.

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DEPUTY DIRECTOR POSITION AVAILABLE

The University of California, Irvine is recruiting a physician scientist for a tenured position at the associate or full professor level who will also be the Deputy Director of the Cancer Center. We are seeking an experienced translational scientist with an established research program focused on either basic/translational investigations or clinical/translational science. This is a senior leadership position within a National Cancer Institute designated Comprehensive Cancer Center. Responsibilities of the selected individual would include:

- (1) Conducting a translational research program with external peer-reviewed funding.
- (2) Bridging basic, clinical and cancer control research among the 6 research programs with the goal of facilitating translational programs, P0-1s, SPORes and similar multi-investigator grants and contracts.
- (3) Providing senior leadership for the physician-scientists and clinical investigators in the Center.
- (4) Managing the clinical research infrastructure within the center.
- (5) Representing the Cancer Center throughout the campus and greater community.

As the current long-term Director has announced his departure from this role following the next CCSG review, responsibilities of the Deputy Director will expand in the near future to include transitioning the Center with new leadership.

Applicants must hold an MD or equivalent degree, be board certified in their cancer related sub-specialty, and be eligible to obtain an active license to practice medicine in the state of California.

For more information, contact Krista Hollinger, MPH at kholling@uci.edu.

Application Procedure: Interested candidates must submit a cover letter, curriculum vitae, statement of research, statement of teaching, and contact information for 3-5 references via the University of California's Academic Personnel RECRUIT system at <http://recruit.ap.uci.edu>. Please reference OEOD# 5012.

The University of California, Irvine has an active career partner program and an NSF ADVANCE Program for Gender Equity and is an Equal Opportunity Employer committed to excellence through diversity.