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Decisively Positive Swedish Study of PSA Becomes Focus in Debate Over Screening

By Paul Goldberg

Any way you look at it, the study of prostate cancer screening in Göteborg, Sweden, stands out—either as an example of a highly effective intervention, or, possibly, as a fluke.

No study comes close to this Swedish randomized trial in producing a robust case for prostate cancer screening.

The trial enrolled 20,000 men in 1994 and screened half of them with prostate-specific antigen tests every two years, ultimately cutting prostate cancer mortality by almost half over 14 years.

Now, as prostate cancer experts debate the recent recommendations of the U.S. Preventive Services Task Force, a lot is riding on the Göteborg study.

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Britain's Cancer Czar Begins Examination Of Risks and Benefits of Mammography

The British National Health Service has initiated a review of its breast cancer screening program.

The review was announced by Mike Richards, the UK National Cancer Director, in a letter to the British Medical Journal.

The review is a response to an open letter from Susan Bewley, consultant obstetrician at King's College London, in which she urged Richards to initiate a review of the evidence on benefits and harms of breast screening.

Bewley argues that NHS leaflets "exaggerated benefits and did not spell out the risks."

"The oft repeated statement that '1,400 lives a year are saved' has not been subjected to proper scrutiny."

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In Brief

Goldberg Named OSUCC Physician-In-Chief; FDA Awards $2 Million To DC-Area Centers

RICHARD GOLDBERG was named physician-in-chief at **the Ohio State University Comprehensive Cancer Center**–Arthur G. James Cancer Hospital and Richard J. Solove Institute.

Goldberg comes to Ohio State from the University of North Carolina at Chapel Hill, where he was a distinguished professor of gastrointestinal cancer research and the physician-in-chief at North Carolina Cancer Hospital.

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Swedish Trial Contributed To ERSPC's Positive Result

(Continued from page 1)

This is in part because it tested an especially aggressive screening and intervention regimen—and in part because its results were pooled with six other European studies to create the European Randomized Study of Screening for Prostate Cancer, or ERSPC for short.

Being wildly positive, the Göteborg trial plays a decisive role in ERSPC. Conduct an exploratory analysis of the European study by tabulating it without the Swedish results, and the entire pooled study loses statistical significance.

And without the Göteborg study and ERSPC, there is no randomized trial that shows that PSA screening saves lives.

Also, at the moment, there is no way to know what happened in the other six ERSPC studies since the Swedish investigators are so far alone in publishing their results. The Göteborg results appeared in The Lancet Oncology in August 2010, almost a year-and-a-half after publication of the ERSPC results in The New England Journal of Medicine on March 26, 2009.

This is not lost on USPSTF. A comprehensive review of evidence that accompanies the recommendation of the independent group of experts convened by the U.S. government reads:

"Although no other center separately reported results, only exclusion of the Swedish center data from the overall ERSPC analysis resulted in loss of the statistically significant effect of screening on prostate cancer-specific mortality… suggesting better results than the other centers."

The paper is posted at: http://www.annals.org/content/early/2011/10/07/0003-4819-155-11-201112060-00375.1.full?sid=c8dec4e1-83cd-42f7-9e4b-1745cf20d5fb

"Could there be anything in the Göteborg study which could have produced such a difference?" said Peter Boyle, president of the International Prevention Research Institute in Lyon, France. "Could such a difference be real? Or could bias have played some sort of role?"

"If Sweden weren't around, we'd have a more consistent answer," agreed Stephen George, professor of biostatistics and bioinformatics at Duke University and director of the Duke Translational Medicine Institute. "I don't know why that is."

"All eyes are on Sweden," said Otis Brawley, chief medical and scientific officer at the American Cancer Society and a long-time critic of mass screening for prostate cancer. "If you accept it as positive, the Swedish study demonstrates that you need to have a rigorous program of screening, a low threshold for biopsy and a low threshold for treatment."

Also, you also have to consider the remaining six ERSPC studies.

The studies conducted by ERSPC's seven centers were very different in the way they selected, randomized, screened and treated patients. Generally, meta-analysis is better suited to make sense of disparate data, critics say. However, the European trial was not intended to be a meta-analysis. It's a pooled study, where each center is free to report its results after the data were pooled are reported.

Simply measuring ERSPC's statistical significance with and without the Swedish result isn't good enough, said Colin Begg, attending biostatistician at Memorial Sloan-Kettering Cancer Center.

"Göteborg is the most positive center. There is going to be a most positive center in any trial," Begg said to The Cancer Letter. "You cannot judge a trial by doing a test excluding every center when there is a relatively small number of centers. The right way to determine if the Göteborg trial is an outlier would be to look at the actual mortality differences within each center and to test for heterogeneity to see if there is any reasonable evidence that the centers are fundamentally different. If you can't establish heterogeneity, then it's not right to do a test excluding Sweden. The right conclusion is

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the analysis including all people who were randomized to this study."

The ERSPC result "is not overwhelmingly convincing evidence, but it's just interesting," Begg said. "It's encouraging. It's not to be dismissed easily."

Brawley concurs that the Swedish trial may suggest a benefit from very aggressive screening and treatment.

"But the Swedish trial clearly suggests significant overdiagnosis, and significant overtreatment, and significant co-morbidity associated with that," Brawley said. With the inclusion of six ERSPC sites that haven't reported their data separately, "what we now have is 11 randomized studies, one of which is very positive, but all 11 demonstrate the harms of screening," Brawley said. "That's the most optimistic, pro-screening statement that I can make."

Göteborg: An Aggressive Approach

The Göteborg study showed a massive biopsy rate—90 percent of men who had abnormal PSA were biopsied, almost three times the rate reported at a U.S. randomized trial.

Overall, 293 men needed to be invited to screening and 12 diagnosed to save one life. This is spectacularly better than the overall ERSPC, where 1,410 men needed to be screened to detect 48 cases of prostate cancer and prevent one death.

As political battles over PSA screening in the U.S. heat up, some prostate cancer experts are starting to see ERSPC as a study that pools a negative and mildly positive trials with the decisively positive Swedish study.

This is puzzling, they say, because the biases in ERSPC were more likely than not to push results toward a positive outcome. Also, a very similar study in Sweden has come up negative. That study randomized 1,494 men in the city Norrköping and included a less rigorous screening regimen, performed every three years, with interventions starting at a higher PSA levels.

That study, by Gabriel Sandblom *et al.*, was published in The British Medical Journal on March 31.

Jonas Hugosson, the principal investigator of the Swedish ERSPC component study and a urologist at the Institute of Clinical Sciences in the Sahlgrenska Academy at the University of Göteborg, said the two Swedish studies are very different.

"There are several important differences," Hugosson said in an email to The Cancer Letter. "The most important difference is probably the length of FU. In the Göteborg study it was 14 years compared to much shorter in most other ERSPC centers.

"The Göteborg study is also much more intense compared to both ERSPC and the [Norrköping] study (which was not designed to study mortality).

"In Göteborg, men have been screened every second year and a PSA cut off at 2.5 has been used. Ninety percent of men with elevated PSA have been biopsied, which for example is far from the situation in PLCO.

"Treatment in the Göteborg study is probably much more aggressive compared to the [Norrköping] study although almost half of men had primary surveillance. There are also other differences as for example age at inclusion that may contribute."

PSA screening requires an aggressive follow-up regimen and longer time before mortality benefits appear, said Gabriel Sandblom of the Karolinska Institute, the principal investigator on the Norrköping study.

"Even if the circumstances in the population where the Göteborg and Norrköping screening trials were, as far as we can see, almost identical, we have come to very diverging conclusions," Sandblom said.

"I believe that at least 10 years, and preferably 20 years, of follow-up are necessary before the impact of a screening trial on disease-specific survival can be seen," Sandblom said in an email. "Such a trial should also be done in a population with little background contamination of opportunistic screening.

"The Göteborg trial was done with shorter screening intervals and lower PSA threshold. The treatment was also more aggressive than in the Norrköping trial. This probably explains why mortality was reduced more effectively in the Göteborg trial, albeit to the cost of overdiagnosis and overtreatment."

The juxtaposition of the two trials, as well as Sweden's high prostate cancer rate, are worth noting, said Boyle.

"It could be argued that since the death rate from prostate cancer is so much higher in Sweden (140.3 per 100,000 at ages 65-74) than in other countries where

screening trials have been conducted (Netherlands (97.4), Finland (92.6), the United States (67.6)), that an intervention could be more likely to be positive there than elsewhere," Boyle said. "However, although much smaller Norrköping trial did not produce a significant outcome.

MSKCC's Begg said the ERSPC trial is making him reconsider his stance on prostate cancer screening.

"This trial is making me more open-minded about prostate cancer screening," Begg said. "I've always thought that the harms clearly outweigh the benefits.

"But the results of this trial have made me step back a little bit and think that it may not be as black-and-white as that. Furthermore, the death rates from prostate cancer seem to widen the longer the follow-up goes on in Göteborg."

"The number needed to treat and the number needed to screen is huge. A vast amount of people get diagnosed as a result of the screening. However, the results do provide quite strong evidence of a mortality benefit, and that's not an unbelievable conclusion.

"This suggests that the risk/benefit trade-off may be favorable for groups of people at very high risk of prostate cancer."

Randomization Problems in ERSPC?

The USPSTF described ERSPC as a "fair- quality" trial.

It assigned randomly assigned 182,000 men aged 50 to 74 years from seven countries to PSA testing every two to seven years or to usual care.

Levels of PSA for diagnostic evaluation ranged from 2.5 to 4.0 mcg/L. Recruitment and randomization procedures and age eligibility also varied.

After a median of nine years, prostate cancer incidence was higher in the screened group (net increase, 34 per 1,000 men), but there was no statistically significant difference in prostate cancer–specific mortality (RR, 0.85 [CI, 0.73 to 1.0]).

A prespecified subgroup analysis of 162,243 men aged 55 to 69 years found that screening was associated with reduced prostate cancer-specific mortality (RR, 0.80 [CI, 0.65 to 0.98]; absolute risk reduction, 0.07 percentage point).

Inclusion criteria and randomization in ERSPC followed different patterns.

In some ERSPC sites, investigators had to get informed consent from all participants. These include: Belgium, the Netherlands, Spain and Switzerland.

In Sweden, Finland, France and Italy, participants could be identified in registries and not informed about being invited to take part in the trial.

In countries that don't require consent for these studies, men in the screened groups would know only that they were being invited to take part in screening while men in the control group would know nothing at all.

"I have ethical concerns about people who are participating in a clinical study not knowing that they are participating in a clinical study," said Brawley. "Perhaps I don't understand the culture of those countries and it may be inappropriate as not a citizen of those countries to be commenting."

The randomization method where participants don't know they are in a trial can also lead to biases, experts in clinical trials say.

With no systematic contact with controls identified through population registries, investigator would be unable to exclude men who have prostate cancer from the control group.

Thus, from the outset, men with prostate cancer would be eliminated from the screened group more thoroughly than from the screened group.

"Having controls not knowing is a push toward a finding that screening saves lives," Brawley said.

This impact can be offset by another bias, which occurs when controls—not knowing that they are controls—go out and get screened for prostate cancer, Duke's George said.

"People who are supposedly in the controls will probably do things that will be similar to what's in the screening group," George said. "Some will contaminate the control group. If there was a positive effect of screening, that would be a bias in the conservative direction, making the screening look not as good."

If screening indeed saves lives, these controls could benefit from the interventions, narrowing the gap between the screened and unscreened arms. (Crossover to screening was a problem in the prostate component of the NCI PLCO trial, where 52 percent of men, despite knowing they were in the trial, obtained screening off-protocol.)

In ERSPC, men in the screened group were probably more likely to be referred to specialty centers after receiving a diagnosis of prostate cancer.

"In some of the ERSPC sites some of the men didn't know that they were in a clinical trial and therefore, if diagnosed with prostate cancer, they did not get treated in the same sites as the men who were on the screened arm," Brawley said.

The "healthy volunteer effect" could push the result toward a positive finding, too. "If all the guys who

go onto the screened arm are guys whom you would treat aggressively if diagnosed with prostate cancer while a bunch of guys who are in the control group are guys who have chronic obstructive pulmonary disease, hypertension and bad cardiovascular disease," Brawley said. "Then you have a disparity between the two groups.

"The bias from the healthy volunteer effect, I suspect, did exist in the positive Swedish study, but it's a bias that would be very difficult to manage," Brawley said. "They would have to know everything about every man going into the trial in order to get rid of the healthy volunteer effect."

A lack of blinding can further compromise the results, Boyle said.

"Autier and colleagues (Recent Results in Cancer Research 2003; 163: 254-263) examined the findings from three randomised trials of Faecal Occult Blood screening for colorectal cancer which had been conducted in Minnesota (USA), Nottingham (United Kingdom) and Funen (Denmark)," he said. "In Nottingham and Funen, the control group was unaware that they were in a study.

"Of course, in such a situation patients allocated to the screening group and their physicians are aware of their trial status whereas this knowledge was absent among the controls and their patients. Having had the trial explained to them and having read and signed an informed consent to participate, awareness of colorectal cancer and its symptoms would be very different among members in the two groups.

"In Minnesota, better awareness of gastrointestinal symptoms resulted in 22 percent of control subjects with colorectal cancer being diagnosed with a Dukes' A tumour compared to 11 percent in both Nottingham and Funen. Removing the bias introduced by colorectal cancer awareness resulted in the initial (statistically significant) 16 percent reduction in colorectal cancer mortality being reduced to the (non-statistically significant) 12 percent reduction in the Nottingham and Funen trials. Although not a principal endpoint in evaluating screening, the five-year survival rate from colorectal cancer diagnosed in the control group in Minnesota (59 percent) was considerably greater that that in the control groups in Nottingham (38 percent) and Funen (32 percent).

"It would be useful to make the same analysis in the case of prostate cancer and to focus on the prostate cancers in the control groups in Göteborg and the stage distribution, and survival, of the interval cancers," Boyle said. "Until then, the possibility of a substantial contribution of bias to the overall results cannot be ruled out."

Pooling of data presents a problem, too, Brawley said.

"The pooling would mask the fact that you have one very positive study and six negative studies. In meta-analysis you would know the result of each of the seven studies, and then you would combine them," he said.

Meta-analysis can be better than pooling as a tool for interpreting disparate results, George said.

"There are biases probably all over the place in all studies, but that at least damps some of them out," he said. "For example, early in breast cancer, you had a lot of negative trials, but when you add them altogether, and it's slightly positive, that's a good thing. It means that in those diseases where a lot of people are involved, a slight benefit is worthwhile to know about."

Of course, it's unlikely that all ERSPC studies would be published separately, observers say.

"That's yet another bias—publication bias," George said. "If you have a wildly positive result, it's likely to be published in a prominent journal. Negative studies have trouble getting published.

"There needs to be a journal of boring results somewhere."

Disclosure: ACS Chief Medical and Scientific Officer Otis Brawley and The Cancer Letter Editor and Publisher Paul Goldberg are co-authors of a book, How We Do Harm: A Doctor Breaks Ranks About Being Sick in Americ a, scheduled for publication on Jan. 31, 2012 by St. Martin's Press.

PSA Screening

AUA Urges Members To Write Congress Opposing PSA Recommendations

The American Urological Association is getting ready for a Congressional fight over the draft recommendation by the U.S. Preventive Services Task Force lowering the grade of the prostate-specific antigen screening test from I, inconclusive evidence, to D.

The downgrading would mean that the task force has determined with "moderate or high uncertainty that the service has no net benefit or that the harms outweigh the benefit" (The Cancer Letter, Oct. 6, Oct. 13).

The association is circulating a letter suggested as a guideline for doctors, "to use in crafting a strong letter to your lawmaker regarding the U.S. Preventive Services Task Force's recommendations for prostate-specific antigen testing."

"Please consider including the following

information to personalize your letter," the document states.

According to the association, this can be accomplished by including the following details:

• "How common is prostate cancer in your area? Be sure to localize your letter."

• "Is your lawmaker a prostate cancer survivor? If he is, appeal to his own experience—did a PSA shed light on his cancer early?"

• "How long have you been in practice treating prostate cancer patients? How do today's statistics compare to the pre-PSA era?"

The text of the sample letter follows:

Dear Lawmaker,

Last week, the U.S. Preventive Services Task Force (USPSTF) dealt a strong blow to prostate cancer patients, urology researchers and the millions of men who may ultimately benefit from the prostate-specific antigen (PSA) test. We need your help.

By downgrading the test to a Grade D, asserting that there is "moderate or high uncertainty that the service has no net benefit or that the harms outweigh the benefits" and discouraging the use of the test, the USPSTF puts many men, including those at a higher risk of developing prostate cancer (African American men, those with a family history of the disease, those who are underinsured and those who live in rural areas with limited healthcare access), at a strong disadvantage against this potentially devastating disease.

These recommendations could potentially limit coverage for the PSA, leading many men to forgo the test and risk developing aggressive prostate cancer. I shudder to think that we could return to the days of the pre-PSA era when men presented with prostate cancer so advanced that treatment options were limited to palliative care.

It is unfortunate that the USPSTF felt the need to issue such a blanket statement for an issue that remains so individualized. The American Urological Association (AUA) believes that the issue of prostate cancer testing deserves a discussion between a man and his physician, and I agree.

Simply put, not all prostate cancers are life-threatening, nor do all prostate cancers require treatment. However, we cannot treat what we cannot diagnose – and currently the PSA test is the only widely available diagnostic for prostate cancer. In order to move forward in advancing our work in the diagnosis of prostate cancer, we need to focus resources on developing a new, more-specific test, not disparaging the only one that is widely available.

Consider these statistics: One in six men will be diagnosed in his lifetime. The American Cancer Society estimates that in 2011, more than 240,000 new cases of prostate cancer will be diagnosed, and that nearly 33,000 men will die of the disease.

Men who are tested for prostate cancer have a far lower mortality rate than those who are not. Consider how that number could change if testing were not available.

I strongly urge you to send a letter of outrage to Health and Human Services Secretary Kathleen Sebelius and demand that she reject the USPSTF recommendations on PSA testing. It would be barbaric to universally dismiss the PSA test before a suitable alternative to prostate cancer diagnosis is available. There are many men in your community who would tell you that a PSA test saved their life.

Sincerely,

[Insert Your Name Here]

The letter is posted at http://www.capwiz.com/aua/issues/alert/?alertid=54422496

UK Begins Independent Review Of NHS Breast Screening Program

(Continued from page 1)

Replying to the letter, Richards said that "screening programmes should be based on the best available evidence" and that "the ongoing controversy should, if at all possible, be resolved."

"Should the independent review conclude that the balance of harms outweighs the benefits of breast screening, I will have no hesitation in referring the findings to the National Screening Committee and then ministers. You also have my assurance that I am fully committed to the public being given information in a format that they find acceptable and understandable and that enables them to make truly informed choices," Richards wrote.

The letter from Bewley is posted at http://www.bmj.com/content/343/bmj.d6894.full

The letter from Richards is posted at http://www.bmj.com/content/343/bmj.d6843.full

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Amgen Agrees To Settle Aranesp Suit, Reserves $780 Mil For Settlement

By Lucas Thomas

Amgen Inc. has agreed to settle several criminal and civil investigations that accuse the company of using illegal sales and marketing practices in promoting the red-blood-cell building agents Aranesp and Epogen. Amgen is setting aside $780 million to pay settlements.

"We announced an agreement in principle with the U.S. government to settle allegations relating to certain sales and marketing practices, which have been the subject of previous disclosures," said Amgen CEO Kevin Sharer, during Amgen's third quarter earnings call on Oct. 24. "We recognized a $780 million reserve in anticipating and finalizing this settlement, which should happen in the next three to four months."

Most of the whistle-blower lawsuits are sealed. One lawsuit that was made available was filed by Kassie Westmoreland, a former Amgen sales representative and Aranesp product manager. The lawsuit was joined by 18 state-level attorneys general.

The lawsuit accuses Amgen of placing excessive amounts of Aranesp into containers and, as part of their marketing, told healthcare providers that they could sell the excess medication and profit from the sale.

The complaint and court documents are posted at http://www.cancerletter.com/categories/documents.

It alleges that Amgen overfilled Aranesp to compete with Procrit, a rival drug. According to court documents, the overfill in Aranesp prescriptions was higher than those of Procrit. Though Procrit is marketed by Johnson & Johnson, it's produced in the U.S. by Amgen.

The lawsuit was filed in late 2009 (The Cancer Letter, Nov. 6, 2009).

A court document showing an Amgen spreadsheet lays out the financial gains that doctors were encouraged to capitalize on, via the overfilled prescriptions.

Amgen "conspired to encourage medical providers to purchase Aranesp based on representations of the profits that the providers could realize from submission of inflated Aranesp-related claims to Medicare," and "encouraged medical providers to overstate the amount of Aranesp administered so that the provider could achieve greater amounts of reimbursement form Medicare and/or Medicaid, thereby making Aranesp more attractive than competitive drugs," the lawsuit states.

Several current and former Amgen executives have been subpoenaed. Five former Amgen executives pled the Fifth Amendment during their depositions, regarding questions of their employment at Amgen.

The states involved in the lawsuits include Georgia, California, Delaware, Florida, Hawaii, Illinois, Indiana, Louisiana, Michigan, Nevada, New Hampshire, New Mexico, New York, Tennessee, Texas, Massachusetts, and Virginia, as well as the District of Columbia.

CDC Committee Recommends HPV Vaccinations For Boys

An advisory committee to Centers for Disease Control and Prevention earlier this week recommended vaccination of all 11- and 12-year-old males against human papilloma virus.

The CDC Advisory Committee on Immunization Practices Oct. 25 voted eight in favor, five against, and one abstention to recommend immunization of boys in order to prevent anal and head-and-neck cancers. CDC usually follows the committee's recommendations.

"The HPV vaccine is a strong weapon in cancer prevention. The quadrivalent HPV vaccine prevents the types of HPV that cause cervical cancer in women as well as anal cancer and genital warts in both women and men," said Anne Schuchat, director of the National Center for Immunization and Respiratory Diseases, during a conference call following the vote.

In June 2006, the ACIP recommended HPV vaccine for 11- to 12-year-old girls and also for teen girls and young women through age 26 who hadn't already received the vaccine.

In October 2009, quadrivalent HPV vaccine was approved for use in boys and young men.

The quadrivalent HPV vaccine is covered for both girls and boys through the Vaccines for Children Program.

On Oct. 25, ACIP recommended that routine vaccination of males aged 11 or 12 years with three doses of quadrivalent HPV vaccine be given to prevent HPV infection and HPV-related disease. Vaccination could begin as young as age 9 and that boys and young men 13 to 21 years of age who hadn't already received the vaccine should also be vaccinated.

About 20 million Americans are infected with HPV, CDC officials say. HPV has been associated with several types of cancer, including cancers of the cervix, vulva, vagina, penis, and anus, as well as head-and-neck cancer. Each year in the U.S. about 18,000 HPV-associated cancers affect women. Cervical cancer is the most common type of HPV-associated cancer in women.

About 7,000 HPV-associated cancers each year affect men in the United States. Cancers of the head

and neck are the most common type of these cancers in men. HPV can also cause genital warts in both men and women, and about one in 100 sexually active adults in the United States has genital warts at any one time. So these are common conditions. Men who have sex with men and people who are infected with HIV are at the highest risk for HPV-related disease.

More than 80 percent of anal cancers are caused by the HPV types included in the vaccine. There have been increases in head-and-neck cancers and in cancers of the anus over the past few decades. Cervical cancer trends have been decreasing over the past few decades, but the increasing trends in these other cancers was something that was important to the committee.

The vaccination is not being highly taken up by teenage girls, CDC officials said.

HPV vaccination of males offers an opportunity to decrease the burden of HPV-related disease in both males and females, officials said.

"So in addition to providing direct benefit to boys by preventing future genital warts or anal cancer there is also the potential that vaccinating boys will reduce the spread of HPV from males to females and reduce some of the HPV-related burden that women suffer from," Schuchat said.

The committee also undertook an extensive review of data on vaccine safety. In mid-September of this year, nearly 40 million doses of HPV vaccine had been distributed in the United States.

Clinical trials that have been carried out in smaller numbers have shown the quadrivalent HPV vaccine to be safe for males as well as for females. The most common adverse events or side effects that can occur following HPV vaccination include injection site reaction, headache and fever. Those reactions have tended to be mild or moderate in intensity.

SU2C and PCF Plan To Create Prostate Cancer Dream Team

Stand Up To Cancer and the Prostate Cancer Foundation, along with the American Association for Cancer Research, have called upon the cancer research community to submit Letters of Intent to create a new Dream Team dedicated to prostate cancer research.

The SU2C-PCF Prostate Dream Team Translational Cancer Research Grant will provide funding of up to $10 million over a three-year period for a cancer research project that will address therapeutic interventions for advanced prostate cancer with special emphasis on metastatic disease, and deliver near-term patient benefit through research by a multidisciplinary, multi-institutional dream team of expert investigators.

Proposals for the dream team research grant must include plans indicating how the work will be translated into the clinic.

To maximize creativity, innovation and collaboration, the team must include laboratory and clinical researchers, senior and/or young investigators and senior scientists who have not worked together in the past, as well as patient advocates.

Collaboration among separate dream teams is greatly encouraged—including an approach that promotes the sharing of information and a focus on measurable milestones of progress.

A SU2C-PCF Joint Scientific Advisory Committee will conduct a unique, rapid evaluation of the applications through a multi-step review process.

The committee is chaired by Nobel Laureate Phillip Sharp, institute professor at the David H. Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology.

It is co-chaired by SU2C representative William Nelson, the Marion I. Knott director and professor of oncology, and director of the Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University, and PCF representative Howard Soule, executive vice president and chief science officer of the Prostate Cancer Foundation.

The advisory committee is comprised of senior laboratory researchers, physician-scientists and patient advocates.

AACR is responsible for administering these grants and provides ongoing scientific oversight.

Those interested should submit Letters of Intent detailing their best ideas for cutting-edge prostate research projects using the proposalCENTRAL website at https://proposalcentral.altum.com.

ProposalCENTRAL will be available by Nov. 15. Letters of Intent must be submitted by 12:00 p.m. ET on November 28.

For general information on eligibility criteria, the application process, or other details about this grant, visit: http://www.aacr.org/SU2CPCF.

Other inquiries may be directed to the SU2C Grants Office at: (267) 765-1049 or su2c@aacr.org.

Plans are to announce the new dream team at the AACR annual meeting in Spring 2012 in Chicago.

In Brief

Goldberg Named OSU Chief Physician; FDA Awards $2 Mil to Georgetown and University of Maryland Centers

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He is also chair and CEO of the ARCAD US Foundation, co-chair of the Society of Translational Oncology, and former chair of the NCI Colorectal Task Force.

"As physician-in-chief for The OSUCC–James, Dr. Goldberg will be instrumental in leading our preparation for and transition into the new James Cancer Hospital and Solove Research Institute, opening in 2014," said Michael Caligiuri, director of the Ohio State cancer center and CEO of the James Cancer Hospital and Solove Research Institute.

Goldberg will lead a medical staff of more than 100 surgical, medical and radiation oncologists and assist in efforts to open the new 276-bed, 21-floor cancer hospital.

THE OHIO STATE UNIVERSITY announced the naming of **The Stefanie Spielman Comprehensive Breast Center**, in honor of the Ohio State alumna, philanthropist and advocate.

According to university officials, the center is the only one of its kind in the Midwest to offer full breast cancer care, from prevention and screening through detection, diagnosis and treatment.

"First and foremost, Stefanie made a difference in the lives of countless patients and their families in the fight against cancer," said Ohio State President E. Gordon Gee. "She touched those struggling with their diagnosis and treatments, helping to make their worlds more comfortable, more optimistic, and more affirmative. She possessed an uncommon combination of bravery, grace, and compassion that continues to resonate through her remarkable legacy."

Stefanie Spielman graduated from The Ohio State University in 1989 with a journalism degree. During a self-examination at age 30, she discovered a lump that was diagnosed as cancer by doctors at the Ohio State University Comprehensive Cancer Center–James Cancer Hospital and Solove Research Institute.

Stefanie and her husband Chris, an All-American linebacker during his playing days at Ohio State, set out to raise money for breast cancer research at OSUCCC-James. In the first year, they raised more than $1 million, four-times greater than their original goal. The Spielmans also raised awareness for the need for breast exams and early detection.

The Stefanie Spielman Funds (www.spielmanfund.com), including the Stefanie Spielman Fund for Breast Cancer Research, the Stefanie Spielman Fund for Patient Assistance, The Stefanie Spielman Chair in Cancer Imaging, and The Spielman Breast Cancer Tissue Archive Services and Spielman Breast Cancer Tumor Bank, have raised more than $9.1 million to date.

FDA announced the award of $2 million to support two regional **Centers of Excellence in Regulatory Science and Innovation**.

The centers, located at the University of Maryland and Georgetown University, will focus on strengthening science and training needed to modernize and improve the ways drugs and medical devices are reviewed and evaluated, a major focus within the FDA.

In August 2011, the agency released the strategic plan for: "Advancing Regulatory Science at FDA" (http://www.fda.gov/ScienceResearch/SpecialTopics/RegulatoryScience/ucm267719.htm).

More recently, the agency announced a related innovation initiative, "Driving Biomedical Innovation: Initiatives for Improving Products for Patients" (http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm274333.htm).

"These partnerships represent a critical, necessary and creative investment—one that will benefit not just FDA and academia, but also American consumers and industry," said FDA Chief Scientist Jesse Goodman, "The Centers of Excellence will create new scientific research, training and staff exchange opportunities for FDA and leading area institutions."

Working closely with FDA scientists, CERSI researchers will assist the FDA in driving innovation in medical product development as well as in advancing laboratory, population, behavioral, and manufacturing sciences. The agency said it chose to pilot the CERSIs in the Washington DC, area, to allow for the greatest possible face-to-face collaboration and training with FDA staff.

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