THE CANCER LETTER

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

Vol. 37 No. 35
Sept. 23, 2011

ODAC's Dilemma

Proposed Indication Created by Reliance on PSA Screening, Hormonal Treatment

By Paul Goldberg

"Non-metastatic castration-resistant prostate cancer" would be an indication like no other.

The population of patients who fit into this category was created by widespread use of controversial detection and treatment strategies, and now at least two companies are developing drugs to treat such patients.

Here is how America's prostate cancer doctors created this category of disease:

Men get diagnosed with early-stage prostate cancer, almost always with the blood test for prostate-specific antigen.

They get surgery or radiation, and many also receive gonadotropin-

(Continued to page 2)

Research Funding

Possible Government Shutdown Looms Over Biomedical Research Funding Once More

The federal government is once again moving toward a shutdown, as the House and Senate are unable to agree on a funding resolution for the new fiscal year, which begins Oct. 1.

Republicans in the House passed a short-term continuing resolution Sept. 23 that would fund the government through Nov. 18, about seven weeks, with about $1.043 trillion. Senate, controlled by Democrats, voted down the resolution.

The House resolution tied federal disaster relief funding to offsetting cuts in programs that Democrats advocate, such as loan guarantees for

(Continued to page 9)

In Brief

Two Cooperative Groups Renamed ECOG-ACRIN, Leaders Developing Administrative Framework

ECOG-ACRIN Cancer Research Group is the new name of the merged Eastern Cooperative Oncology Group and The American College of Radiology Imaging Network.

The two groups announced their merger last May.

"We are already actively engaged in the shared mission of reshaping the future of patient care through clinical research that leads to earlier cancer detection, more successful therapeutic intervention, greater rates of prevention and more successful patient outcomes," said ACRIN Chair Mitchell Schnall

(Continued to page 8)

PSA Screening Controversy "Trickles Down" To New Indication

(Continued from page 1)

releasing hormone agonists, or androgen-deprivation therapies, often off-label.

Hormonal treatments are approved for palliative treatment of advanced disease, and they have been shown to slightly improve survival for clinically advanced, localized disease when combined with radiation therapy. Though not on the label, this is a reasonable use.

However, doctors have been using these drugs more widely, as an adjuvant treatment, and epidemiologists estimate that a third of American cancer patients have had them at some point in their disease.

The hormones are prescribed to 60,000 to 70,000 new patients per year. Altogether, at least 250,000 men receive these drugs, each paying $800 a month, sometimes even after their PSA starts to rise again.

When the patients' PSA begins to rise despite treatment with hormones, the indication is born: you have a heterogeneous population of men exhibiting something called "PSA anxiety." Most of these patients will die of something else many years later, but some will indeed go on to die of prostate cancer.

Earlier this month, when FDA asked the Oncologic Drugs Advisory Committee to consider the would-be indication, prostate cancer expert Derek Raghavan put the issue in a nutshell. "I don't want to open a can of worms, but let's remind ourselves that we still haven't agreed on screening utility of PSA," Raghavan, president of the Levine Cancer Institute at the Carolinas HealthCare System in Charlotte, said at the ODAC meeting Sept. 14. "So that just trickles down at each stage of disease."As the patients' PSA starts to climb, physicians are left stumped.

Is this just a rising lab value or is this a clinically definable disease? Should androgen-blocking drugs be continued despite their failure to suppress PSA? Nobody knows, and with no trials underway, no reliable answers are expected.

To the industry, this indication could be worth billions, assuming that FDA would be willing to recognize non-metastatic castration-resistant prostate cancer as a bona fide indication.

So far, at least two drugs have emerged as candidates, but experts say that many more are on the way. Amgen's agent for Xgeva (denosumab), which would be used to treat men with castrate-resistant prostate cancer to reduce the risk of developing bone metastases. The target date for the agency to act is April 26, 2012.

Xgeva, a fully human monoclonal antibody that binds to RANK Ligand, is approved for prevention of skeletal-related events in patients with bone metastases from solid tumors. The drug is also approved under the trade name Prolla as a treatment of osteoporosis in postmenopausal women who have an increased risk for fractures and are intolerant of or refractory to another osteoporosis medicine.

Meanwhile, Exelixis, a biotechnology firm, is developing an agent called Cabozantinib (XL184) for indications that include castrate-resistant non-metastatic prostate cancer.

The results from the company's phase II trials were presented at the most recent annual meeting of the American Society of Clinical Oncology (http://www.exelixis.com/sites/default/files/ASCO_2011-XL184-CRPC.pdf). The drug has not been submitted to FDA.

New Indication Raises Old Questions

Now, consider the dilemma the agency is facing:

"The population of patients with non-metastatic, castrate resistant prostate cancer (NM-CRPC) is not an FDA sanctioned patient group," Mark Schoenebaum, a biotechnology and pharmaceuticals financial analyst with ISI Group, wrote in an email to clients.

"In other words, the FDA has NEVER approved hormone deprivation therapy for patients who do not have clinical or radiographic metastatic disease. Thus, the FDA is concerned that by approving drugs in this patient population, that it will effectively endorse this

THE CANCER LETTER

® The Cancer Letter is a registered trademark.

Editor & Publisher: Paul Goldberg
Copy Editor: Conor Hale
Intern: Lucas Thomas

Editorial, Subscriptions and Customer Service:
202-362-1809 Fax: 202-379-1787
PO Box 9905, Washington DC 20016
General Information: www.cancerletter.com

Subscription $395 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.

unapproved use of anti-androgens."

Indeed, the agency has opposed many of the practices that have combined to create this indication.

For one thing, FDA has never accepted the lowering of PSA as a surrogate endpoint for drug approval.

It is also unclear whether the agency would accept an increase in PSA as a defining characteristic of a population of patients.

The second characteristic of the proposed indication—off-label use of hormones—has also been of interest to the agency. (Indeed, the only labeled indication of these drugs, the palliative setting, usually concludes with the patient's death, and thus cannot produce a "castration-resistant" population.)

A year ago, FDA asked the sponsors of gonadotropin-releasing hormone agonists to add warnings to the labels of this class of drugs.

The new label, announced Oct. 20, 2010, warns about increased risk of diabetes, heart attacks, sudden cardiac deaths and strokes. Since there is no ongoing trial to answer scientific questions of toxicity of these drugs, the negative data are being generated in observational studies (The Cancer Letter, Feb. 5, 2010, May 7, 2010, Oct. 22, 2010).

These measures were feasible because increases in adverse events can be seen in several cancer registries.

At the same time, cause-specific mortality from prostate cancer has been dropping for the past two decades, and this drop has added up to about 30 percent since 1990.

The worst-case scenario explaining this drop would be that patients who would have ordinarily died of prostate cancer die earlier of strokes and heart attacks.

This would not be the first time for the agency's oncology unit to confront a loosely justified, widespread medical practice. In recent years, the agency clamped down on the common and lucrative practice of over-prescribing erythropoiesis-stimulating agents to treat anemia in cancer patients.

This latest drama will unfold against the backdrop of continuing controversy over screening for prostate cancer. Two new developments are expected to occur in the next few months:

• Sources said that the U.S. Preventive Services Task Force stands poised to update its recommendation on screening for prostate cancer. The date of release of the recommendation is not publicly known.

• The NIH Office of Medical Applications of Research is planning a "state of the science" meeting on management of prostate cancer. The details are posted at http://consensus.nih.gov/2011/prostate.htm.

In Search of Patient Benefit

At the meeting Sept. 14, FDA asked ODAC to discuss the standards for approving drugs for the proposed indication, but stopped short of asking the committee members to cast votes.

After reviewing FDA briefing document, Schoenebaum noted that FDA argues that "not only is the use of ADT not approved for this population, but the FDA's 'bias' is that it doesn't work."

"This creates a difficult regulatory conundrum," Schoenebaum wrote.

The FDA briefing document is posted at http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/OncologicDrugsAdvisoryCommittee/UCM271470.pdf

FDA's questions to ODAC—like a judge's instructions to a jury—often point to a menu of possible answers.

The text of the questions follows:

The committee will consider the development of products for the treatment of patients with non-metastatic, PSA-only recurrent prostate cancer who have not received androgen deprivation therapy (ADT) and for the treatment of patients with non-metastatic castration resistant prostate cancer (NM-CRPC) who have a rising serum level of prostate-specific antigen (PSA) despite currently receiving ADT.

Non-metastatic castration-resistant prostate cancer (NM-CRPC) is a result of the use of androgen deprivation therapy (ADT) in patients with a rising serum prostate-specific antigen (PSA) after primary local therapy for prostate cancer.

NM-CRPC is characterized by asymptomatic increases in PSA with no radiographic or clinical evidence of metastases despite continuation of ADT.

There are no randomized clinical trials demonstrating that early use of ADT in patients with non-metastatic, PSA-only recurrent prostate cancer provides clinical benefit. In contrast, long-term use of ADT can result in serious adverse reactions, including increased risks of developing diabetes, osteoporosis or fracture, fatal cardiovascular disease and decreased muscular mass contributing to frailty.

1. Discussion

Issues Concerning Patient Population: Discuss what populations of patients with non-metastatic, PSA-only recurrent prostate cancer who have not received ADT and patients with NM-CRPC are appropriate for trials intended to support approval of products for these indications.

If clinical trials should be limited to patients at

high risk for prostate cancer morbidity or mortality, please discuss how the high risk population(s) should be defined. Two types of randomized trial designs are proposed to assess the effectiveness of a product in these patient populations.

Trial Design 1 is a "Concurrent Comparison" that compares the product to placebo or an appropriate comparator. Possible endpoints include asymptomatic metastasis-free survival, symptomatic metastasis-free survival, and overall survival.

Trial Design 2 is an "Early versus Delayed" treatment comparing the efficacy of early treatment initiation of the product in the asymptomatic non-metastatic, PSA-only recurrent prostate cancer population who have not received ADT or the asymptomatic NM-CRPC setting to delayed treatment with the same product started after clinical metastases become evident.

This design is not appropriate for investigational products with no known efficacy in metastatic prostate cancer. The question is whether early treatment with a product already approved in the metastatic setting is better than delayed treatment with the same product.

2. Discussion

Issues Concerning Trial Designs and Endpoints: Discuss the use of different study designs in asymptomatic non-metastatic, PSA-only recurrent prostate cancer who have not received ADT and asymptomatic NM-CRPC along with endpoints to be used for each type of design (e.g. overall survival, metastasis-free survival, and symptomatic metastasis-free survival) and patient population.

For Trial Design 2, please also discuss potential disease progression criteria (e.g. evidence of metastasis, PSA progression, and symptoms) to initiate delayed treatment.

There are no products currently approved for these indications.

No specific products will be presented or discussed; rather, the committee will be asked to consider possible patient populations, trial designs and suitable clinical endpoints for studies intended to support approval of a new product or a new indication.

Unanswered Questions in Prostate Cancer

The meeting began with two talks focused on the cohort of castration-resistant patients and risk stratification that may make it ethical to conduct useful studies in such patients.

The two talks were given by Joel Nelson, the Frederic N. Schwentker Professor and chairman of the Department of Urology at the University of Pittsburgh School of Medicine, and Howard Scher, the D. Wayne Calloway Chair in Urologic Oncology and chief of the genitourinary service at Memorial Sloan-Kettering Cancer Center.

Prostate cancer experts on the committee generally agreed that the highest-risk patients have the PSA doubling time of three months or less.

This is based on a 2003 study by D'Amico et al., which suggested PSA doubling time, following prostatectomy or radiation treatment, as a surrogate endpoint for prostate cancer. According to that paper, patients with a PSA doubling time of three months or less account for about 22 percent of patients treated for prostate cancer. The paper is posted at http://jnci.oxfordjournals.org/content/95/18/1376.short.

In his talk, Scher urged the committee to focus on truly high-risk groups, such as patients who had received hormonal agents after their PSA started to climb, following surgery or radiation. The question of overtreatment is a separate one, he argued. However, the committee members quickly focused on overtreatment with hormonal therapy. As a result, the discussion quickly turned into a parade of unanswered questions in the treatment of prostate cancer.

Should hormonal treatment begin immediately after the patients' PSA starts to go up? Or should patients start receiving treatment after they develop clinical symptoms?

Should treatment continue after progression?

"I am going to be a little heretical here. I don't think true adjuvant trials have ever been done in prostate cancer," said ODAC member Deborah Armstrong, associate professor of oncology at the Sydney Kimmel Cancer Center at Johns Hopkins University. "You just haven't had much to use except androgen deprivation therapy.

"Are there any adjuvant trials going for true adjuvant therapy—that are not for the PSA rise? In breast cancer, we don't continue hormonal therapy when it failed. In the adjuvant setting, we have data that combining hormonal therapy with cytotoxic actually has antagonistic effect.

"This whole concept of why you are continuing something when it wasn't working? Is it because it's

rising, but it would be rising faster if you didn't continue the therapy? Is there data on that? Or is it the idea that stopping would cause more PSA anxiety?"

Mario Eisenberger, a temporary voting member of ODAC, acknowledged that many key questions in prostate cancer haven't been answered.

"When we say that hormonal therapy does not prolong survival, in reality we don't know," said Eisenberger, the R. Dale Hughes Professor of Oncology at Johns Hopkins. "It has never been tested. The models of where this has been tested in the past involves patients in a different era, different time, different ways of managing. And the paradigm is moving further and further. I am afraid that at this time we are not going to have the opportunity to assess the role of early vs. delayed hormone therapy. We've missed the opportunity."

Unanswered questions notwithstanding, a large number of patients now need some sort of treatment.

"I don't see how one would not treat it with hormonal therapy today if you are sitting in the clinic, like I do, and the patient comes in, and the PSA is 1, and three months later that PSA is 12," Eisenberger said. "How can you not treat that patient somehow?

"It's a fact of life: we are dealing with a group of patients who start hormonal therapy and now have a rising PSA. We probably have now about half a million men walking around out there, getting hormonal therapy, with a rising PSA.

"So what do you do with them? Some of them you may not have to do anything with. But if they have a short PSA doubling time and they will develop bone metastases, they will die of prostate cancer. So why not consider a reasonable evidence of bone metastases in these men?"

Raghavan said the prostate cancer field is politicized and often not driven by data.

"Practices vary, practitioners vary," he said. "I think in the practice community and in the academic community there is no homogeneity of opinion. The reality is, as one looks at this population of patients, the really well-designed, hard data are very poor.

"If I am trying to make decisions here, in the utopian view or the purist view, we need more trials to answer the questions, as has been mentioned several times.

"A very significant part of this is the advocacy community that find it intolerable to sit by and watch PSAs rise. And that may be consequence of the fact that we have educated them poorly, or as likely the consequence of the fact that there isn't unanimity among the medical professionals.

"Urologists will tend to be much more PSA-driven than medical oncologists."

ODAC member William Kelly, professor of medical oncology at Thomas Jefferson University, agreed.

"It's very heterogeneous out there," said Kelly. "I spend most of my time talking people out of therapy than in therapy. And there are lots of drivers that cause people to pull the trigger. And I think there is a little difference between academics and the community, because sometimes it is easier to treat patients than to talk about what would be appropriate.

"But at the end of the day, we don't have good data to guide us. And that's the bottom line. We don't get adequate trials to tell us what to do."

"Three Months is Nonsense. Less is Even Crazier…"

ODAC Chair Wyndham Wilson said the studies would have to address either survival or quality of life.

"I always have trouble with endpoint that don't either improve survival or quality of life," said Wilson, chief of the Lymphoma Therapeutics Section at the NCI Center for Cancer Research.

"I recognize that such new therapies can impact survival in a randomized study," Wilson said. "I guess my question would be whether time to metastatic disease is a reasonable endpoint.

"If you are treating someone and your trial hasn't gone on long enough to know whether your drug has an overall survival advantage or doesn't have one, you want to make sure that whatever surrogate you have chosen either is improving that person's quality of life, or you are absolutely convinced that down the line—four or five years later, way beyond your trial—that it is going to improve overall survival.

"We have to make sure that we are really helping folks and not, basically, getting a radiographic finding."

Scher said researchers have no good way of tracking the disease. The objective is to predict how changes in the bone can predict a clinical event. Ultimately, the studies would have to address hard endpoints, he said.

"I think the trials have to be designed in such a way that we can answer these questions, whether we are talking about serum or imaging," Scher said. "There is no good way to understand what the significance is of

---

any change that we see ultimately means."

The treatments for the castration-resistant non-metastatic indication can be diverse, Scher said,

"I am not sure how you can practically implement a delay trial in a patient population that is getting a biologic versus a hormonal therapy, versus one that is getting a cytotoxic," he said. "You can't lump them all together.

"If you think about reimbursement in the non-metastatic castrate setting, what's the trial that you need to do that? If the trigger comes too early, they are not going to see the survival advantage.

"So does it mean it doesn't work or it did?"

Raghavan said a one-year delay in progression could be regarded as meaningful.

"What we can do today is paint a broad canvas," he said. "We can't design the trials around this table. So we can make some broad statements to guide the FDA. So the first statement is: you have to think completely differently about new versus hormone-resistant disease These paradigms are different.

"For the patient who previously hasn't had hormones, probably the driver is the [Edward] Messing study in the adjuvant setting, published in the New England Journal [http://www.nejm.org/doi/full/10.1056/NEJM199912093412401], and subsequently updated, that show that early intervention for locally extensive tumors makes a difference to survival.

"It's a big one. It changes the context of whether you delay or not delay. That's a totally different setting from a patient who is progressing on hormones. So the first this is, we need to divide those two.

"The second is: there will not be a perfect answer for what is okay for delaying metastases. I personally think a meaningful endpoint would be a year.

"I think a year is nice and clean. It allows you to identify a real biologic link. The down side of setting a year is that you will miss a smaller biological impact. But it's a reasonable point. And so at some point the FDA is going to have to say how big an impact for anything that we want to see.

"Three months is nonsense. Less than three months is even crazier.

"The third point I would make is that we all indicated a consensus that in the patient who is on hormones and has a doubling time of less than three months, irrespective of any other prognostic variable, those patients would die fairly quickly, and they have an urgent need.

"The final point I'd like to make—I really have to take issue with the statement, unsupported by data, that it would be unethical to discontinue hormonal therapy. I heard strong advocacy for continuing hormones. The reality is, I have never heard diabetes advertised as a good thing. And the fact of the matter is, there are no data that it is unethical or inappropriate to discontinue treatment.

"Rather poor studies have been published that suggest that continuous and intermittent androgen deprivation are equivalent. The definitive study has not yet been reported. So the absence of data here is not informative.

"Throughout the country, for a range of reasons, physicians and patients will discontinue hormonal therapy when a patient is in remission, and there are no published data to suggest that in observed situation it's a bad thing.

"I make the point, because this is on record, and it would be a shame to have malpractice attorneys running off and advertising, 'If you had hormones discontinued, call 1-800-TRIAL ATTORNEY.'

"It's a ridiculous statement unsupported by data."

ODAC member Brent Logan focused on potential endpoints in greater detail.

"There was some discussion about time to systematic metastasis," said Logan, associate professor of biostatistics at the Medical College of Wisconsin.

"It seems to me that this has direct clinical meaning—the time to metastasis itself. But in order to implement it, you need to do some of what you do for the survival endpoint. The patients are not going to wait for intervention until they get to systematic metastasis.

"So this requires continuous follow-up in order to provide an intervention after the initial metastasis develops. It requires longer-term follow-up similar to what's done for survival, except it's a little more complicated.

"In terms of defining a magnitude of benefit like time to metastasis as a potential surrogate endpoint, I think a lot of it hinges on the duration of metastasis to death.

"If it's a long duration of time, then you will need a longer potential benefit in the time to metastasis in order to better predict for a survival benefit. Also, it's important to remember that what's considered a clinical benefit depends on the toxicity of the intervention.

"There was a mention of the potentially high incidence of the competing risk of death without metastasis, particularly in these older patients. It seems to me that rather than time to metastasis, it would be better to use metastasis-free survival, because it includes the potential impact of the interventions on toxicities, which would then be reflected in non-metastasis mortality.

"That may better correlate with overall survival as well.

"One final comment on early vs. late design—where treatment has been approved at metastasis. Here, you can't use metastasis-free survival. You need to use overall survival or perhaps time to symptomatic metastasis."

JANE ZONES [acting consumer representative, of Breast Cancer Action]: "As for the claim that discontinuation for this group would be unethical, I am remembering that almost the entire medical establishment made this claim that it would be unethical to deprive post-menopausal women of hormone replacement therapy by randomizing them into a placebo group.

"And we know what happened there."

EISENBERGER: "For us to do clinical trials and go against what most people consider standard of care is asking for failure.

"We are now going to be asking patients who standardly are receiving hormonal therapy to stop it in order to do the trial, I think we are making requirements more difficult. Not to say that your questions don't have any scientific merit—they do.

"But we are trying to focus on a group of men with high-risk disease and now they a biochemical relapse, low levels of testosterone, and their PSA has gone up again. I don't know whether stopping hormone therapy is a benefit, but it's so unlikely that this will be accepted in the clinical trials community that we are asking for failure.

"I also think that to ask the question of can you do something in that patient population to delay the onset of metastatic disease is a very pertinent clinical question. This is an unmet medical need. This is a huge patient population."

KELLY: "We talk about metastatic development of bone metastases as systematic. The major symptom patients develop in this disease is fatigue, not bone pain.

"So we have to be very careful in how we define symptomatic metastatic disease. The other one is using survival as an endpoint. If you use these drugs very early, you have new treatments down the line and there is no consistency in what order we use them.

"I have no idea how to sort out the impact of these additional treatments down the line. So I am very concerned that survival would not be a viable endpoint. I am not at all sure that we will be able to tease all that out."

RICHARD PAZDUR [director of the FDA Office of Oncology Drug Products]: "We see this in every disease, and we see this in drugs that may come up. We have a randomized study here.

"So, one would have to assume that in a randomized study, new therapies are allocated in a random fashion to each arm. Remember, we are approving a drug in the context of existing therapy, so these are existing therapies that are there. I think the CTEP people recently wrote an article on looking at survival as a pertinent endpoint in any disease setting.

KELLY: "Rick, but the point I am trying to make is that we are dealing with a very heterogeneous population.

"There are treatments out there that are approved that are better in some of these populations than the others.

"Unfortunately, we don't know which groups are best to do it in. So there are a lot of variables to consider, and to put a lot of weight on survival may be concerning."

In Brief

ECOG-ACRIN Merges Activities Into Three Core Research Areas

(Continued from page 1)

and ECOG Chair Robert Comis in a joint statement at the 2011 ACRIN annual meeting Sept. 23.

The two cooperative group chairs said they merged their activities into three core areas of emphasis: early detection and diagnosis of cancer; biomarker-driven phase II and phase III therapeutic studies for multiple cancer types and stages; and genetic, molecular and imaging marker research to predict and monitor treatment response.

Schnall and Comis said they expect ECOG-ACRIN to achieve together what was not possible separately, "through the bold integration of disciplines and technologies." They went on to say that the new group offers "the unique capacity to conduct definitive, groundbreaking, biomarker-driven clinical research that promises to achieved patient-centered breakthroughs."

The group leaders are developing the business, administrative and scientific framework for ECOG-ACRIN to sustain its combined research portfolio through public and private support.

Research Funding

Senate Appropriations Proposes $190 Million Budget Cut for NIH

(Continued from page 1)

alternative energy programs. Unless a deal is made, the government could shut down on Oct. 1.

In a statement, Senate Majority Leader Harry Reid, of Nevada, said the House bill wasn't "an honest effort at compromise."

"It fails to provide the relief that our fellow Americans need as they struggle to rebuild their lives in the wake of floods, wildfires and hurricanes, and it will be rejected by the Senate," Reid said. "Instead, they moved even further towards the Tea Party. They insist on holding out on Americans who have suffered devastating losses. Americans are tired of this partisanship.

"They deserve to know that when disasters strike, we will be there to help them. The American people should not have to worry that the relief they need will get tied up in partisan gridlock.

"The Senate is ready to stay in Washington next week to do the work the American people expect us to do, and I hope the House Republican leadership will do the same."

* * *

The Senate Appropriations Committee passed a bill that will cut the NIH budget by $190 million, or 0.6 percent.

This is the second consecutive year that medical research funding has been decreased.

The proposed NIH budget now stands at $30.5 billion for 2012. "Cutting NIH is not a choice I wanted to make," said Sen. Tom Harkin (D-Iowa), chair of the subcommittee that drafted the bill.

"But a 0.6 percent cut to NIH is something that I think they can live with," said Harkin.

The proposed bill did not provide a completely dismal outlook for NIH. It includes money to fund the National Center for Advancing Translational Sciences—an establishment that NIH director Francis Collins has championed.

"We are mindful of the current budget environment, but sustaining robust funding for cancer research must be a national priority, and we urge Congress to restore full funding for the NIH and NCI in a final spending bill," said Christopher Hansen, president of the American Cancer Society Cancer Action Network.

"Despite the tough budget environment, ACS CAN is pleased that the committee reaffirmed its commitment to key cancer prevention programs at the Centers for Disease Control and Prevention that will help save lives and avoid the high cost of treating advanced disease," Hansen said.

The report is posted at: http://1.usa.gov/plpDHy

* * *

The American Association for Cancer Research earlier this week released a "cancer progress report" calling for more support for cancer and biomedical research.

The document calls for a five percent increase above the biomedical inflation rate for the NIH and NCI.

"Unfortunately, with each passing day, our ability to capitalize on the nation's longstanding investment in cancer research seems to elude us as a result of flat and declining funding for the NCI and NIH," said AACR President Judy Garber, director of the Center for Cancer Genetics and Prevention at the Dana-Farber Cancer Institute.

The progress report stresses the need to continue advances in cancer research, by focusing on supporting innovative research; developing a network of tissue banks; developing informatics platforms and linking physical sciences and engineering with cancer biology.

To achieve these goals, the report circles back to the need for increased funding to translate research into treatment.

The report can be found at: http://bit.ly/q1LVE0

* * *

The Milken Institute, an independent economic think tank, has released a report entitled "The Global Biomedical Industry: Preserving U.S. Leadership." The report outlines what U.S. policymakers must to do adapt to the changing field of biomedicine.

The report states that the biomedical industry accounts for roughly five million U.S. jobs. The industry includes $70 billion in wages and another $200 billion in economic output.

As the international market evolves and other countries emerge as potential leaders, the report points to seven necessary steps that policymakers must take to remain competitive, including: increasing research and development tax incentives and make them permanent; cutting corporate tax rates to match the OECD average; enhancing support for emerging fields; providing adequate resources for the FDA and the NIH; leverage existing strengths in medical devices; building human capital; and promoting and expanding the role of universities.

— Lucas Thomas

DON'T MISS THE NIH STATE-OF-THE-SCIENCE CONFERENCE

ROLE OF ACTIVE SURVEILLANCE IN THE MANAGEMENT OF MEN WITH LOCALIZED PROSTATE CANCER

CONFERENCE QUESTIONS

1. How have the patient population and the natural history of prostate cancer diagnosed in the United States changed in the last 30 years?

2. How are active surveillance and other observational strategies defined?

3. What factors affect the offer of, acceptance of, and adherence to active surveillance?

4. What are the patient-experienced comparative short- and long-term health outcomes of active surveillance versus immediate treatment with curative intent for localized prostate cancer?

5. What are the research needs regarding active surveillance (or watchful waiting) in localized prostate cancer?

DECEMBER 5–7, 2011

NATCHER CONFERENCE CENTER
NATIONAL INSTITUTES OF HEALTH, BETHESDA, MARYLAND

INFORMATION/ REGISTRATION:
CONSENSUS.NIH.GOV
CONSENSUS@MAIL.NIH.GOV
888-644-2667