THE



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NCI Director Sets A Goal: Eliminate Suffering, Death From Cancer By 2015

NCI Director Andrew von Eschenbach has a goal: "to eliminate the suffering and death from cancer by 2015."

This goal figures as the key element of a strategic plan currently under development at the Institute, von Eschenbach said to the National Cancer Advisory Board Feb. 11.

"I have set out—and it has been embraced, I'm pleased to say—a challenge goal that shapes our mission and shapes our vision," von Eschenbach said to the board. "And the challenge goal that we have (Continued to page 2)

In Brief:

Zerhouni Appoints Behavioral Scientist **Raynard Kington As Deputy Director**

RAYNARD KINGTON was appointed NIH deputy director, succeeding Ruth Kirschstein, NIH Director Elias Zerhouni said Feb. 10. Kirschstein served deputy director since 1993, and acting NIH director from January 2000 to May 2002. She will become the senior advisor to the NIH director. Kington has served as NIH Associate Director for Behavioral and Social Sciences Research and director of the NIH Office of Behavioral and Social Sciences Research since November 2000. He also served as the acting director for the National Institute on Alcohol Abuse and Alcoholism from January to September 2002. Kington came to NIH from the Centers for Disease Control and Prevention. As director of the Division of Health Examination Statistics in the CDC's National Center for Health Statistics, he led the National Health and Nutrition Examination Survey, a survey of the health status, health behaviors, and diet of people in the U.S. Before joining CDC, Kington was a senior scientist at the RAND Corp., where he co-directed the Drew/RAND Center on Health and Aging. . . . JNCCN, the Journal of the National Comprehensive Cancer Network, has published its first issue. The goal of the quarterly publication is to improve communication between academic and community oncologists, said William McGivney, CEO of NCCN. Information is available at www.nccn.org. . . . HOWARD SCHER has been named the incumbent for the D. Wayne Calloway Chair in Urologic Oncology at Memorial Sloan-Kettering Cancer Center. . . . THE CANCER INSTITUTE of Kansas City, Mo., has received a \$200,000 translational research laboratory grant for its Division of Cancer Research. Given by the Glass Family Foundation, the grant will be managed by the Saint Luke's Hospital Foundation.

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NCI Director Says Goal To End Suffering By 2015 Feasible

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accepted as an Institute is to eliminate the suffering and death due to cancer, and to do it by 2015." Von Eschenbach said the goal includes solving health care delivery problems and eliminating health disparities.

By setting an ambitious goal on the threshold of what is likely to be a period of modest budgetary increases, von Eschenbach is taking a controversial step in a field that has a history of unrealistic promises.

An argument can be made that NCI owes its current \$4-billion budget—the largest of the NIH institutes—to the "war on cancer," the public relations and legislative effort that led to the National Cancer Act of 1971. However, many observers argue that the rhetoric used to increase funding for cancer research also led to heightened public expectations for quick cures, and resulted in disappointment when the cures didn't materialize. Two previous NCI directors, Samuel Broder and Richard Klausner, set no deadlines for curing cancer, and deliberately avoided the war metaphor.

The Institute's new goal provoked no reaction from the NCAB. The board members did not use the question-and-answer session that followed von Eschenbach's remarks to discuss the goal. Instead, discussion focused on plans for funding investigator-



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initiated grants under the Bush Administration's proposed 3.5 percent increase for NCI for fiscal year 2004.

"We need to have goals," NCAB Chairman John Niederhuber said when asked by a reporter about the 2015 target. "All of us would like to do it next year, or next week. What you heard this morning was an impressive and ambitious agenda."

Several oncologists and cancer activists contacted this week declined to comment on feasibility of the Institute's goal, saying that they needed further information about von Eschenbach's plans.

An American Cancer Society spokesman said the society did not want to comment without viewing a transcript of von Eschenbach's remarks. In 1996, ACS published a book titled "Horizons 2013: Longer, Better Life Without Cancer," that suggested it would be possible to achieve a 45-percent decrease in the age-adjusted death rate for cancer by 2013, the year that ACS turns 100.

Von Eschenbach, formerly a surgeon at M.D. Anderson Cancer Center, had been slated to serve as the society's president prior to his NCI appointment. He was one of the founders of the ACSled National Dialogue on Cancer, which seeks to bring together cancer organizations to develop a common agenda.

3D's: Discovery, Development And Delivery

"I did not say that we would eliminate cancer by 2015," von Eschenbach said in his remarks to the NCAB. "We are committed, and we are pledged to working collaboratively and collectively together to eliminate the suffering and death due to this disease."

To accomplish this, NCI has developed a strategy that von Eschenbach called "the three D's: Discovery, Development and Delivery." The NCI strategic plan has identified goals in each of the three areas, he said.

"Within the portfolio of discovery, our long-range objective is that we will ultimately have defined all of the relevant mechanisms that are responsible for the initiation and progression of cancer, in the cancer cell, in the person, and in populations," von Eschenbach said. "Based on that new knowledge and understanding, we will have developed effective interventions that predict, detect, diagnose, treat, and prevent the disease.

"We will assure that those interventions are delivered as state-of-the-art care to all of those in need, and to do that with special reference to being

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able to deliver it in the context of clinical trials, so that the very delivery process itself develops and evolves new knowledge in our understanding of the malignant phenomenon," von Eschenbach said. "We will do that in the context also of making sure that all populations are addressed and benefited, and that requires a special effort in the elimination of disparities."

NCI has used its professional judgment budget, known as the Bypass Budget, to lay out year-to-year funding priorities. The new NCI strategic plan will take a longer view, and include short-term, intermediate, and long-term goals, he said. The plan will be used to establish new programs and initiatives.

NCI will invite outside comment on the plan as it is being developed, von Eschenbach said.

"Like Putting a Man on the Moon"

In an interview, von Eschenbach said he believed that it is possible to achieve the 2015 goal.

"It's an ambitious goal, no question," he said to **The Cancer Letter**. "But if you look at the trajectory we are on, there has been an incredible explosion in our understanding of cancer and in the rapidity with which we can process data, and in the technology that is enabling us to do gene expression analysis.

"It almost mimics Moore's Law for chips," he said, referring to the prediction by Intel founder Gordon Moore that the number of transistors on a chip can be doubled every two years.

"Therefore, I believe it's not unrealistic to extrapolate that exponential growth that we can develop enough interventions that we may be able to prevent people from suffering and dying from the disease," von Eschenbach said.

"That is a goal we should establish, and it is like putting a man on the moon in a decade. We can make it a reality. I believe we have to do it. I'm not trying to offer false hope or expectations. But I do think we have to set goals.

"What I'm laying out there is the commitment. I don't have a crystal ball, but I do believe we can make the commitment."

Beware The "Cycle of Euphoria And Despair"

The comparison with the space program is part of the rhetorical tradition in cancer politics.

Activists who lobbied for the Cancer Act likened the quest for a cure for cancer to the 1960s space program effort to put a man on the moon. In 1970, to build momentum for the Act, Congress passed resolutions calling for a cure for cancer by 1976, the Bicentennial.

In the 1980s, NCI set forth the "Year 2000" goal of a 50-percent reduction in cancer-related mortality. After taking criticism for making too many promises, the Institute stopped referring to that goal well before 2000.

Since 1971, "oncologists and cancer patients have been caught in a cycle of euphoria and despair as the prospect of new treatments has given way to their sober realities," wrote Jerome Groopman, the Recanati Professor of Medicine at Harvard Medical School, in The New Yorker (June 4, 2001).

"Three decades later, the high expectations of the early seventies seem almost willfully naïve," Groopman wrote. "This year alone, more than a million new diagnoses of major cancers will be made and about 550,000 Americans will die of cancer, an average of 1,500 a day.... All the same, the triumphalist rhetoric that animated the war on cancer still shapes public opinion: many people believe that cancer is, in essence, a single foe, that a single cure can destroy it, and that the government is both responsible for and capable of spearheading the campaign. The military metaphors have retained their potency—even thought they have proved to be inappropriate and misleading."

According to Groopman's article, steady progress in scientific discovery, rather than directed research, is the most promising route to eventually improving cancer morbidity and mortality.

Robert Cook-Deegan, a science historian, former executive director of the Institute of Medicine's National Cancer Policy Board, and director of the Center for Genomic Ethics, Law and Policy at Duke University, similarly cautions against setting unrealistic goals.

"I think useful 'grand challenges' come in two flavors," Cook-Deegan said to **The Cancer Letter**. "One is the kind that David Hilbert proposed for math at the turn of last century, which poses interesting and important problems that shed light on fundamental holes in the fabric of knowledge. Another kind of grand challenge is the kind that J.C.R. Licklider and others at Defense Advanced Research Projects Agency posed for technology. Those were scale or scope expansions that seemed just beyond the horizon, but might be possible with enough resources and new ideas. That worked very well in computing. Arguably, it has worked sometimes in biology, like mapping and sequencing the genome in 15 years starting in 1990.



"Solving cancer, however, is a practical and clinical problem, not a purely scientific one. We simply don't know if the solution is science or technology. It seems most likely it is only partly science and technology. Moreover, the problem of cancer seems very hard indeed for science, although we can never know this in advance, and it is surely well beyond current technologies.

"Eliminating suffering from cancer by 2015 seems like it would require eliminating cancer by 2015, either by preventing it all or by having fully effective treatments for all cancers," Cook-Deegan said. "Things are moving fast, but eliminating cancer seems pretty out there, and unless the challenges are really well grounded in the science or technology, I fear that what it invites is regret in 2016, when the historians of biomedical research look at the promise.

"Reading Steve Strickland's book, `Dread Disease,' or Dick Rettig's book, `Cancer Crusade,' would augur caution about promising to eliminate cancer in particular," Cook-Deegan said. "Been there, haven't done that.

"The statements of 1971 looked silly when the deadline passed in 1976. I don't think the rhetoric did a lot of harm, but I don't think it did any good, either. The promise was not really sincere. There was at least a little harm in not delivering what was promised. To the degree that credibility matters and I think it does—this is a dangerous game. Dented credibility is not tangible, but it is real, and it affects political clout," Cook-Deegan said.

"I like the spirit of wanting to eliminate cancer in 12 years, but I would ask lots of questions about the scientific and technical grounding."

Text of von Eschenbach's Remarks

The excerpted text of von Eschenbach's remarks follows:

This morning is my one-year anniversary with the NCAB. It was a year ago at this meeting that I came before you as the new director of the National Cancer Institute. I can't get away with that anymore, so I'm not the new guy anymore. And they asked me, How would you know at the end of the year whether you were successful or not?" I imagined that would mean if I was still standing.

I think you will be pleased to know that not only am I still standing, I'm still smiling. This truly has been an absolutely extraordinary year, and has been extraordinary for me from the perspective of continuously coming to fully understand and appreciate the greatness of this organization and the greatness of the people who are within it....

We are, in fact, at a very difficult period of time with regard to our country and the challenges that it faces. There is much that concerns us and therefore impacts upon us. But it's important in that regard to also keep clearly in focus a couple of very important issues that I would want to share with you.

Three months ago, the President, at the White House, at a special ceremony that was intended to honor cancer survivors, made the emphatic statement that for the first time in human history, we can say with certainty that the war on cancer is winnable, and that this nation won't rest until that victory is complete.

That quote reaffirms the incredible commitment and support that we must have as we face other threats throughout the world to not ever lose sight of the extraordinary threat that we all face from cancer, and our enormous responsibility to make good on the promise, and to fulfill the incredible opportunities that are before us because of this nation's investment in cancer research and what has occurred within this institute, and because of this institute, and we remember that there are those who are destined to suffer and die of this disease that continue to look to us to eliminate that threat.

It's also important to realize that subsequently, at a very important session with Andy Card, the President's chief of staff, who spoke to a group of the senior leadership in the Department of Health and Human Services, he reminded us that presidents get elected because they said they would do certain things.

But once they are elected, they don't necessarily get to do the things they said they would. They get to do the things they have to do. This President is faced with having to be responsive to the challenges of the budget, and recession. He is faced with challenges of protecting this country from terrorism, and he is faced with challenges now with regard to our national policies with regard to Iraq.

But Andy Card's point was, that does not mean that the things that he felt extremely strongly about prior to his election—education and health care—are not still extremely important. But as the focus has shifted, our responsibility has not.

It was a reminder to us within the department of how critically important that we stay focused on the issue of health care, and specifically the issue of eliminating cancer...

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I want to tell you about an effort that has been underway for the large portion of the year, my first year, as the director.

It was an effort to bring together the division heads and senior leadership of the NCI to really begin to address long-range strategic planning. The Bypass Budget has been an extraordinary mechanism and has been extremely effective, I believe, in laying out a large portfolio of important initiatives that the Institute was committed to and sought support for. But I thought we could take that process, and broaden it quite significantly, and begin to look at long-range opportunities, and specifically to set in place a longrange mission and objective.

We have been engaged in a number of efforts across the past year with retreats that have been directed and guided by experts, in two areas. One in team building, and we really have put a lot of effort into learning and working effectively, even more than before, in recognizing how important it is for integration across the NCI, as well as the ability to work effectively within the organizational pieces of the division.

But in addition to the team building, the really important effort has gone into long-range strategic planning. Not for the purpose of developing simply a plan, as is usually the case, that then gets stuck on a shelf, but rather to create a process.

The process will enable us to continuously refine and redevelop the strategic plan for the Institute, and to do it in a way that positions us, not only with regard to our own internal operational plan, but also how it interfaces and integrates with the larger agenda that's occurring around us.

One of the things that I think has been quite important from my perspective is to look at where the NCI is today, as compared to where it has been in the past. Even within my own career in oncology, when I began my career in medicine in the late '60s and early '70s, I think it was fair to say that with regard to the world of oncology, the NCI was the universe.

There was very little else out there with the exception of a few cancer centers. But, in fact, what occurred was this incredible resource began to populate and create throughout the entire rest of the country this enormous enterprise that we now have within our grasp as a cancer initiative. Therefore, the NCI is no longer the universe, but it truly still remains the center of the universe....

So that has been the focus of the reason for the

process, and I have set out and it has been embraced, I'm pleased to say, a challenge goal that shapes our mission and shapes our vision. And the challenge goal that we have accepted as an Institute is to eliminate the suffering and death due to cancer, and to do it by 2015.

I did not say that we would eliminate cancer by 2015. We are committed and we are pledged to working collaboratively and collectively together to eliminate the suffering and death due to this disease. In order to accomplish that, we have laid out a strategy that embodies the three D's, as we are calling them: Discovery, Development and Delivery.

You've heard me allude to this before, but the strategic planning process has now defined long-range, aggressive, ambitious goals within each of those areas of discovery, development, and delivery, that will ultimately get us to that vision of a world free of the suffering and death due to cancer, by 2015.

Within the portfolio of discovery, our long-range objective is that we will ultimately have defined all of the relevant mechanisms that are responsible for the initiation and progression of cancer, in the cancer cell, in the person, and in populations. Based on that new knowledge and understanding, we will have developed effective interventions that predict, detect, diagnose, treat, and prevent the disease.

We will assure that those interventions are delivered as state-of-the-art care to all of those in need, and to do that with special reference to being able to deliver it in the context of clinical trials, so that the very delivery process itself develops and evolves new knowledge in our understanding of the malignant phenomenon.

We will do that in the context also of making sure that all populations are addressed and benefited, and that requires a special effort in the elimination of disparities.

We have been engaged in defining specific plans and specific initiatives to complement what is already in place, and to focus what's already in place, that will really enable us in a road-mapping exercise, to put into place short-term, intermediate-term, and then long-term objectives and initiatives that will ultimately fulfill those three criteria in discovery, development, and delivery.

You'll appreciate that if we are going to map that kind of roadmap of planning initiatives, that we also have to superimpose upon that a financial plan that will make certain that we are able to have adequate resources to be able to carry out those



initiatives, and that is also a part of our process, to begin to look at mechanisms and ways in which we can plan for appropriate resource acquisition, and resource utilization.

We also have to do this in the context of accountability, and therefore, we will we working to define milestones and outcomes that we can then measure and have metrics to be certain that we are in fact achieving those incremental successes that will ultimately add up to and result in the achieving of our long-range goal.

We also need to do this in the context of the fact that no matter what we do, it will never be done in isolation....

So, the process that we are now embarking upon is to really, for these next months, to focus very intensely upon the NCI's internal intramural program and to crystallize and define it's strategic opportunities so that we add value to the rest of the enterprise.

We will be paying a great deal of attention to the intramural program and the opportunities that present themselves by virtue of the fact that the Clinical Center is going to be opening up in 18 months and we have important opportunities there, and we have also underway an effort to look at the activities and facilities that are up at Frederick and how we might be able to capture strategic opportunities that could be developed there, especially around emerging technologies, and the opportunity to create a biomedical infrastructure of research.

In addition to that, we are also focusing a great deal on how we could integrate the NCI's effort into the larger community. There will be a number of activities underway over these next few months that will be inviting into the planning process, the inputs from the broader community.

We heard reference this morning to Eric Lander joining you as a member of the board. Eric over the past year has been working as a volunteer to help begin to lay out and formulate a process whereby we could begin focus groups to look at longer-range scientific strategic planning.

We are also inviting into our whole process of the Bypass Budget, opportunities for the broader community and organizations to have input early on in the planning process. So those mechanisms for input are underway.

This is also occurring in the context of the fact that there are similar activities that are occurring within the National Institutes of Health, and also within the Department of Health and Human Services. So NCI's planning process is being done in concert with and in conjunction with these other planning processes.

The department has begun its efforts based a great deal on the Secretary's priorities and the President's priorities, but has also worked to define some specific trans-HHS initiatives that would really work as a cross-sectional effort of activity. There have been five that have been specifically identified for immediate attention. The major one, of course, is Medicare reform.

The next one is emergency preparedness. The next one was prevention, and then elimination of health care disparities, and then finally, information technology.

I mention those, because all of them to some degree have impact or implications for NCI, but two in specific will directly involve the Institute in a very important way. The first one being prevention, where the principal focus will not only be on tobacco, but very importantly, on the area of what I describe as energy balance, namely the issue of nutrition and physical exercise, but the overarching concern, of course, is the epidemic of obesity and the implications that has for Type 2 diabetes, heart disease, and cancer.

So the NCI is going to be playing a very integral role in the trans-HHS initiatives to address prevention as it relates to the whole area specifically of energy balance as well as reference to tobacco, as well. That initiative will in a large part be championed by the Surgeon General.

The other area that's very important is disparities and the elimination of health care disparities. In this regard, the department is actually looking to the NCI to provide the infrastructure and the leadership for the launching and support of that initiative.

It will be championed by Claude Allen, the deputy director of the department. We have already been underway with regard to discussions and interactions, particularly with the tremendous support of Cherie Nichols, in building on the great success that's been achieved using the PRG process.

As many of you know, that has been very effective in a variety of ways throughout the NCI, in moving from a strategic plan to an implementation strategy with measurable outcomes and the ability to measure progress. That has been embraced by the department and in fact will be the mechanism that will be used to begin the process of a trans-HHS initiative.

Some of you can appreciate that using cancer



as a model and beginning to focus on this particular area, where we have at the table not only the NCI or NIH, but CMS, CDC, the Surgeon General, ARHCQ, HRSA, and the FDA, presents an extraordinary opportunity to really make a tremendous impact.... This will be a very important initiative for us over the next three months.

We are also working with regard to what's occurring at the NIH. Dr. [Elias] Zerhouni has convened a very extensive road-mapping experience and is focusing the NIH effort in a few particular areas at the outset.

One, to foster interdisciplinary science. He is also looking at new pathways for discovery, which brings in the role of important new technologies, nanotechnology, etc. And then the re-engineering of the clinical research enterprise.

Those initiatives have very direct significance to us at the NCI, because they in fact have already emerged as part of our strategic planning effort. We are looking very much in looking at our process of road-mapping around fostering interdisciplinary science and an initiative on integrative cancer biology, or systems biology, if you will.

We are also paying a great deal of attention to the strategic development of cancer initiatives, especially around the whole area of drug development, but that also extends to interventions that reflect behavioral sciences as well.

And then, we also have an effort at early detection, prevention, and prediction, and we're in the process of looking very much at our clinical research infrastructure.

So, the point is, you can see that the strategic planning process is one that is not simply an initiative that's occurring in isolation within the NCI, but rather, it positions us in a very unique way to play a critical leadership role at the NIH and the Department of Health and Human Services as we really begin to look at efforts that could transform the landscape, not only of cancer care, but of health care in general.

You will be hearing much more from us in the next few months as we unfold a lot of the specific initiatives to bring in your input from the broader community into the road-mapping exercises that will really be defining many of the specific initiatives that we will fold into our other processes like the Bypass Budget and our year-to-year planning activities.

The NCI will have to really work exceedingly hard to define its unique role and contributions, but it will also have to work extremely hard to partner and collaborate with the variety of other components.

We have already been fortunate to start a very exciting dialog with the FDA and its new commissioner Mark McClellan in terms of how we can effectively partner and work together to streamline some of the regulatory issues that are impacting upon our ability to move the pipeline of these new biological interventions to actual interventions that are touching patient's lives.

In the States: NY Sues Drug Companies Over Cancer Drug Pricing

The New York attorney general has accused Pharmacia and GlaxoSmithKline of engaging in "illegal schemes to inflate the price of prescription drugs for consumers and government health plans." A third company, Aventis, has been notified that it will face a similar lawsuit, officials said.

The New York suits filed Feb. 13 claim consumer fraud, commercial bribery, and making false statements to government health plans regarding the pricing of cancer drugs. The action transfers to the courtroom the debate that has so far been confined to federal health agencies and Capitol Hill.

The New York suits are unusual, because they allege that using a formula based on the drugs' "Average Wholesale Prices" to determine billing constitutes illegal activity. The suit differs from recent actions by state attorneys general alleging violations of antitrust laws in the pricing of cancer drugs (**The Cancer Letter**, Jan. 10).

The American Society of Clinical Oncology acknowledges that physicians mark up the drugs they administer in their offices. However, the markup is applied toward other services that are received by cancer patients, yet not appropriately reimbursed by the government, the society says.

"ASCO is hopeful that increased public attention to this issue will lead to Medicare reform that properly reimburses both cancer drugs and cancer care services," said Paul Bunn, the society's president. "A system that's having lawsuits to fix the system is probably a system in need of reform."

The suit against Pharmacia states that the company "makes fraudulent and deceptive misrepresentations that conceal the true average wholesale price from consumers, government agencies and drug price reporting services... As a result of Pharmacia's misrepresentations, doctors and



other healthcare providers are improperly induced to prescribe Pharmacia's drugs, and government payers and consumers... pay artificially inflated sums for chemotherapy and other drugs."

The incentives are intended to influence the physicians' choice of drugs, the complaint states.

"In New York, physicians have fiduciary obligations to their patients, including the duty to use their independent professional judgment in making treatment decisions and not to accept any consideration to alter that judgment," the document states. "Pharmacia creates and markets the spread on its prescription drugs to New York doctors without the consent or knowledge of their patients and with the intent to influence the physicians' choice of drugs to administer or prescribe to their patients."

The suit against Glaxo is nearly identical.

"We are seeking restitution for consumers and the state, and new reforms that will help maintain the integrity of the doctor-patient relationship, by making sure that medical decisions are based on sound clinical guidelines, not on whether a manufacturer's drug delivers higher compensation to a provider," New York Attorney General Eliot Spitzer said in a statement.

ASCO President Bunn said there is no evidence that markup on drugs drives treatment decisions. "There are implications [in the suit] that cancer doctors are behaving inappropriately," Bunn said to The Cancer Letter. "We don't think it's true, but one of the reasons to reform the system is so that there could never be that perception or that reality.

"We have to give a drug dose, based on the patient's condition on that day, based on their liver function, their kidney function, their bone marrow function, whatever side effects they have," Bunn said. "You can't vary from that. If you vary from that, you kill a patient."

If a decrease in reimbursement for drugs is not accompanied with an increase in payment for services, oncologists will stop providing chemotherapy in their offices, ASCO officials say. "Cancer doctors will still see patients, but they will be like pediatricians or psychiatrists," Bunn said. "They will send patients to the hospital, but the hospital will not be able to treat them, because they can't take care of them all."

The suits, filed in Albany County Supreme Court, were posted at <u>http://www.oag.state.ny.us/press/</u> 2003/feb/pharmacia_complaint.pdf

The ASCO statement: www.asco.org.



Experts present updates of the following NCCN Clinical

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