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NCI Director Defends Goal To Eliminate Suffering, Death From Cancer By 2015

As he faced questioning by members of the National Cancer Advisory Board earlier this week, NCI Director Andrew von Eschenbach defended his goal to "eliminate suffering and death from cancer" by 2015.

"We do not believe that it's an unrealistic expectation," von Eschenbach reiterated at the board meeting June 10. "I believe we can look at the American public and the world and set this goal without it being something that is considered unrealistic."

Von Eschenbach first announced his "challenge goal" unexpectedly, in the middle of his remarks at an NCAB meeting last February (**The**

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In Brief:

GM Foundation Prizes Awarded To Jordan, Chang, Moore, Chambon, And Evans

GENERAL MOTORS Cancer Research Foundation presented its 2003 cancer research awards June 11. **V. Craig Jordan** was awarded the Charles F. Kettering Prize for research on the use of anti-estrogens, particularly tamoxifen, for the treatment and prevention of breast cancer. He is the Diana, Princess of Wales, Professor of Cancer Research and professor of molecular pharmacology and biological chemistry at Northwestern University's Feinberg School of Medicine, and director of the Lynn Sage Breast Cancer Research Program at the Robert H. Lurie Comprehensive Cancer Center. **Yuan Chang** and **Patrick Moore** were awarded the Charles S. Mott Prize for their discovery and characterization of the causative agent of Kaposi's sarcoma. The husband-and-wife team is from the University of Pittsburgh School of Medicine, where Chang is professor of pathology and Moore is professor of molecular genetics and biochemistry and director of the Molecular Virology Program at the University of Pittsburgh Cancer Institute. **Pierre Chambon** and **Ronald Evans** were awarded the Alfred P. Sloan Jr. Prize for their work in steroid and nuclear hormone receptors. Chambon is honorary professor at the College de France and professor emeritus at the University Louis Pasteur. Evans is professor at the Salk Institute for Biological Studies and a Howard Hughes Medical Institute investigator. Each prize includes $250,000. In the past 25 years, the foundation has awarded $13 million to 101 scientists. . . . **MICHAEL CALIGIURI**, director of the division of hematology and oncology at The Ohio State University College of Medicine and Public Health, has been selected to direct the OSU Comprehensive Cancer

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NCI's Mantra: "Ready, Fire, Steer," Von Eschenbach Says

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Cancer Letter, Feb. 14). Initially, board members greeted the announcement with uncharacteristic silence.

"The last time I presented this, you were, I think, more stunned," von Eschenbach said earlier this week, acknowledging the February surprise. "That's why I wanted to bring it back, so that we did have the opportunity for discussion…. I welcome critical input. It will help us, not hurt us."

The board responded with a volley of questions: Is there a step-by-step plan? Is the plan realistic? Is NCI abandoning its quest for cancer *cures*? How would you gauge progress?

Von Eschenbach said NCI will not write a prospective plan. Instead, the Institute will rely on an "ongoing strategic planning process," which he said is now in place. "I don't believe in plans that you then put on a shelf," he said. "What we are committed to is a planning process."

However, NCI officials prepared a page-and-a-half-long list of eight "2015 Strategic Planning Priority Areas." A version of the list is posted at http://www.cancer.gov/BenchMarks/archives/2003_04_public/related_article.html.

Every three months, the Institute's leadership meets for a day "as a strategic planning body to look at process," von Eschenbach said.

"Our mantra is: we get ready, we fire, and we steer," he continued. "It's not: ready, aim, fire. It's ready, fire. We are launching. We are moving initiatives ahead that we believe are important strategically to impact on that continuum of cancer process."

The measures of progress are yet to be developed, von Eschenbach acknowledged.

"I would point out that the metrics are not going to occur in a linear fashion," he said. "Just as cancer can be exponential in its growth, the solution to cancer can also be exponential in its realization."

Following are excepts from von Eschenbach's remarks to the board, and the question-answer session:

VON ESCHENBACH: When I spoke to you last, I introduced to you a very important outcome of the NCI's strategic planning process, that outcome being that we had crystallized and had established a very important, long-range strategic goal. That goal was to eliminate the suffering and death from cancer. Looking at that goal, we established a time line in which we would achieve that goal, of 2015.

Subsequent to that, I have had the opportunity to continue to discuss and deliberate in a variety of venues the implications of that goal and the appropriate strategies required for us to achieve that goal. You have received from us a copy of "Benchmarks," in which I attempted to really lay out in much more detail the rationale and underpinning of that goal.

I thought it would be appropriate, in addition to calling your attention to Benchmarks, and inviting you to really look at that in great detail, and take the opportunity to reflect back to me your thoughts and concepts in that regard, I thought it was important to take a few moments this morning as part of my report to you to just touch on a few of the very important pieces contained in that Benchmarks discussion to reiterate some of the rationale behind that goal.

First of all, it's important to once again remind us that the reason why the goal is now feasible is because of the tremendous progress that has been made within our biomedical research enterprise. When one looks at the kind of progress that is being made and what has been achieved since the signing of the National Cancer Act in 1971, I think it's fair to say that one appreciates that this has been a virtual explosion in our awareness and our fund of knowledge of cancer as a disease.

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It's also at this point, I think, important to realize that we are at a moment in which, not only has our fund of knowledge been growing at an explosive rate, but as I alluded to earlier, our critical mass of intellectual capital with regard to the number of researchers who are committed to the cancer enterprise, and, in fact, the resources that are available, from the point of view of fiscal resources and infrastructure, has never been greater. We are at a moment in time where the budget of the NCI is the largest it's ever been. The budget of the NIH and other biomedical research enterprises is likewise at a high-water mark. Certainly, one could always look forward that continuing to grow and increase, because the need is so great, but I think it's important for us, for at least the purposes of realization of where we are, and where we ultimately could go, to realize that we are uniquely positioned at this point to capitalize on that incredible opportunity.

We have within our grasp the resources and the tools. We also have, I think, an important need to focus the goal. Remember that I did not say that we would eliminate cancer. I said we will eliminate the suffering and death due to cancer. The reason why it's important to keep that distinction clearly before us, is because what this progress in biomedical research has led us to, is that for the first time, perhaps, we are really beginning to understand cancer as a disease process, and a process in which there are multiple steps that are responsible both for our susceptibility to the disease, the fact that we at some point in time undergo a malignant transformation, and then, the processes and steps that are responsible for progression of that malignant transformation, to the point in which it becomes clinically apparent, and then, ultimately, to the point where it achieves a lethal phenotype by becoming metastatic and resistant to cell death and therapeutic interventions.

As we have begun to understand cancer as a disease process, we now have multiple opportunities to intervene in that disease process in a way that we can preempt the disease initiation and progression, such that we can prevent patients from ever developing the disease. For others, who do develop the disease, we can detect it in time, and we can eliminate disease. For others, we have the opportunity to begin to manage the progression and the evolution of the disease, such that they live with it, rather than die from it.

We have continued to expand and further develop the portfolio of strategic initiatives that we believe are going to be necessary and central for us to achieve this goal. It will require a collaborative, cooperative, multidisciplinary, integrated effort on behalf of the entire cancer community, for this to be achieved. We have created that effort in the context of a balanced portfolio that continues to look at the elements of discovery, development, and delivery, and will continue to work within the NCI, as well as within the larger context of the cancer community, to continue to drive that agenda.

I hope you will take the opportunity to really look at the issues that have been portrayed in Benchmarks, and I look forward to the opportunity to continue to work with you as we continue to go forward in the planning process and the implementation process to capitalize on the extraordinary opportunity that's within our grasp, and to really begin to revolutionize our ability to deal with cancer as a disease process.

There are a number of initiatives that are underway that I wanted to bring your attention to, with regard to the kinds of things that we are doing with regard to our research process.

You will recall that…the senior leadership of the NCI has been engaged in a series of planning efforts to look at our long-range opportunities. We have begun to focus that on some key strategic initiatives that we will be unfolding over this next year. One of them is in the area of molecular epidemiology. The others are integrated cancer biology; the strategic development of cancer interventions; programs in early detection, prevention, and prediction; integrated clinical trials system; overcoming health disparities; and bioinformatics.

These are going to be key initiatives that we will be embarking upon with regard to specific initiatives that we will look forward to sharing with you as the process continues to unfold. One of the things that I would also make you aware of, is the fact that we are looking at this not only with a contextual effort within the NCI, but also, very importantly, with regard to our opportunities for partnerships and collaborations, for bringing these opportunities about.

One of the very important areas of collaboration and cooperation has been, of course, the emerging effort with the Food and Drug Administration. Those of you who had the opportunity to be at ASCO were present when Mark McClellan and I presented to ASCO, together, our vision for the cooperative effort that we believe is essential for the two institutes or

organizations. The genesis behind this FDA-NCI collaborative effort is the fact that there is already a lot going on within NCI and within FDA, if you will, at the grassroots level, in the effort for the two organizations to work together collaboratively. We also recognized from a leadership perspective that if we were going to, in fact, be successful at our individual missions, that finding more formal and more effective ways of bringing the institutions together in a more focused way was a significant opportunity….

What we came to appreciate was that our missions are different, but we are, in fact, bonded together by a common vision. The common vision, is, in fact, to understand the disease, and then to translate that understanding of disease rapidly into the creation of more effective and safe interventions to truly benefit and serve patients. So benefiting and serving patients is, in fact, our common bond, and finding ways for our two missions to be integrated, coordinated, in a synergistic way, is our commitment.

The process has been done already with the creation of a joint task force between the NCI and the FDA. That task force has already had meetings formally and informally, in small ad-hoc groups, and there is an endless amount of momentum beginning to be generated as the task force is looking at two components of opportunity: one being the creation of programs between the two institutes that would, in fact, facilitate and enhance our ability to collaborate on discovery and development of interventions, and those efforts are going to include a variety of initiatives, including a very important focus on bioinformatics infrastructure and platforms, as well as our opportunities with regard to working together through the validation of biomarkers of intermediate endpoints. We are also going to work together to look at an assessment and evaluation of processes to see how they might be more effectively streamlined to rapidly enhance our ability to move through this continuum of capitalizing on the opportunities in genomics and proteomics for the development of effective interventions. Those interventions having to do with devices and opportunities in early detection, capitalizing on proteomics from the point of view of our ability to detect and predict diseases, and also the whole area of chemoprevention.

We have been very blessed, and I am particularly grateful to Dr. Anna Barker, who as deputy director for strategic scientific initiatives, is co-chairing the FDA-NCI task force on our behalf….

We will continue to participate very actively in a variety of other opportunities, including opportunities that are already present to us with regard to the effort through the National Dialogue on Cancer and other organizations….

RALPH FREEDMAN [NCAB member, professor of gynecologic oncology, M.D. Anderson Cancer Center]: Dr. von Eschenbach, these are really ambitious objectives, the 2015 goal. I think it is certainly important to set goals that have time lines in them, but I also think it's important that we have some realism in these objectives. I think this is important not only to maintain the confidence of the many people who care for and are involved in the care of patients, but for the patients themselves. I just wondered if you could expand perhaps for us what would be the major objectives that you would hope to achieve in this period?

VON ESCHENBACH: That's a very important point, and I appreciate it. Let me just start by saying that I think it's important to keep in mind the framework of reference that I alluded to in which we view cancer as a disease process. When we view it as a process, from the point of view of, even in the phase prior to transformation, we are dealing with issues of susceptibility and carcinogenesis, and then the point where we actually get malignant transformation, and at that point, you have a period of progression of disease to the point where it becomes clinically apparent, and then, the second phase after that, when we go from clinical disease to metastatic phenotype and death. So along that continuum, there are multiple opportunities for us to preempt that process, to the point where we eliminate the burden of cancer and the suffering and death that occurs as an end result of the disease. Our focus is on eliminating the end result by being able to strategically intervene at multiple places throughout that continuum of the cancer process.

We are going to be focusing on the front end as we go through further strategic investments in understanding factors relevant to our susceptibility to cancer, our understanding of host factors, our understanding of the process of carcinogenesis, and opportunities with regard to prevention that can alter or change one's life short of that ultimate malignant transformation. So there's a whole series of strategic opportunities within that phase.

The second phase is once we have cancer to the point where it progresses to clinically apparent disease, again, a very significant series of opportunities for us to strategically look at that phase.

Primarily, even from the perspective of our ability to detect that process much earlier than we are able to, because if we can simply move our ability to detect the presence of cancer much sooner in the course of the disease, we already have effective interventions than can eliminate cancer when it is still early and localized. That, in itself, presents us another set of very important strategic opportunities.

Some of the initiatives, even with regard to proteomics and functional imaging regarding early detection, can bear tremendous fruit in making a significant impact on the lethality of cancers, like pancreatic cancer and lung cancer, for example, where just early detection in itself, and application of currently available, effective therapy can have significant impact on elimination of suffering and death.

Finally, we have a whole significant proportion of that spectrum of cancer process where we have the opportunity to intervene even with regard to the process of metastasis, and malignant phenotype, by not only focusing on the cancer, the tumor, the cancer cell, but its interaction with its micro- and macro-environment. So, our beginning emerging focus on micro-environment, for example, our re-emphasis of the importance of tumor host factors, are another set of strategic opportunities within the portfolio.

As far as realistic expectation, what we have available to us is a very broad spectrum of strategic opportunities. At multiple places and multiple combinations of those interventions, we can deliver on the promise by effectively accelerating our progress across that continuum. Although, when we think about this as a linear extrapolation, one begins to raise questions as to whether you can, in fact, achieve this goal within a finite period of time, if one thinks of it as multifactorial, and multifactorial in a way that is integrated, and has an ability to alter or change the curve, to the point where all we need to do is change the slope of the curve, not eliminate the curve, necessarily in all cases. Some we will. Most, hopefully, we will. But for others, even if we don't eliminate cancer, if we just change the slope of the curve, people will live with, and not die from.

In that context, we do not believe that it's an unrealistic expectation, nor do we believe that the timeline, given what is virtually exponential growth in our knowledge and understanding of cancer, and what is a common growth in our intellectual capital, our financial resources, and the virtual explosion in enabling technologies, that now make it possible to more rapidly, even further accelerate this progress, just looking at what's happening in enabling technologies with regard to computational and information technologies. I often use the euphemism, can you imagine what Einstein could have done with a laptop? Look at what the impact of robotics was on the Human Genome Project.

So, when one looks at it from that broad perspective, then I think, I believe we can look at the American public and the world and set this goal without it being something that is considered unrealistic.

FREEDMAN: I think a lot also depends upon the behavior of the population. We know that, for example, we have done a lot in reducing lung cancer through reduction in smoking, but it's a big challenge to get this issue across to the public at large. We know that even if you stop people from smoking at age 30 or 50, it can have an enormous impact on the reduction of cancer. It seems like this has to be part of it, the participation of the public.

VON ESCHENBACH: There's no question that this strategy has to include every element, every component of the problem. Cancer is a systems problem, and the solution to cancer is going to be a systems problem. This is going to require a very important focus with regard to our understanding of biology of cancer, of cancer cells. It's going to require a very important focus on the person, both from the biologic perspective, as well as the behavioral perspective that you are talking about. It's going to require a focus on populations and population science. This is not going to occur in one particular silo or venue. It's going to require a comprehensive strategy that's looking at all of these components. Where I think we have an extraordinary opportunity, is as that the NCI is uniquely positioned to, one, significantly contribute to the actual research endeavor, while at the same time, provide significant leadership to help coordinate and integrate the larger agenda, that's going to be hard. That's why efforts and initiatives like our partnership with the FDA are an important part of our strategy, because that's ultimately going to be another component to this ultimate solution.

That's why we are working to support a trans-HHS departmental initiative to address the problem of health care disparities and the inordinate burden of cancer, because that's a problem that requires a systems solution, and we need to work effectively with other components of the system—CDC, CMS, etc.—to bring about that piece of it. We are looking

at this, not simply from the tunnel vision of our own portfolio, but also looking at it from the point of view of what we need to do across the continuum of discovery, development, and delivery, to bring it about. Behavioral modification and science is a critically important part of that, just as are our efforts in molecules and biology.

SUSAN LOVE [NCAB member, adjunct professor of surgery, University of California, Los Angeles]: It sounds great, and I think it's a really valid goal, but how are you going to measure it? In 2015 are you going to say, "See, we had no deaths from cancer, any cancer this year." Or are you going to say—or how are you going to measure—nobody suffered this year? You know, saying we are going to eliminate suffering and death from cancer, I don't quite understand what's going to allow you to say, "We did it."

VON ESCHENBACH: Ultimately, there are a couple of metrics that I think are going to have to be developed. I would point out that the metrics are not going to occur in a linear fashion. I'm fond of trying to explain this, is that just as cancer can be exponential in its growth, the solution to cancer can also be exponential in its realization, such that, you know the old story of, what you rather have, a million dollars for a month's work, or a penny on day 1 and double it every day until you get to day 30?

When you think of this as exponential, and I believe that we can track things over the past 30 years, and begin to really see, just as occurred with microprocessors and Moore's Law, essentially almost exponential expansion here, we are somewhere around day 20. We are no longer back at week one, where at the end of the week, you've got $3.50 or whatever it is. We are somewhere in day 20. But the greatest progress is still before us, that latter part.

If you want me to speculate, I think between now and 2007, 2010, our measures are going to be still incremental. We are going to see a continuing decline in mortality due to cancer. We will probably continue to see expansion in number of patients who have cancer, but I believe we will continue to see a decline in mortality, and we need to track and measure that.

We will also be seeing the expansion of the portfolio of our ability to manage the disease, such that prolongation of survival will be another measure. I think that that is an important measure….

As far as suffering is concerned, I do think our ability to manage the burden of the disease and the implications of the disease, is again one that is able to be measured. Ultimately, what we will get to is a point where those people dying from cancer, as a direct result of it, does, in fact, come down to baseline of zero.

JOHN NIEDERHUBER [NCAB chairman, professor of surgery, University of Wisconsin]: As with any strategic planning process, it's important that there be flexibility in that process. I wonder if you would share with us what process you have put in place with your executives, your division leadership, to periodically look at the baby steps within the Institute and how to adjust and react to changing environment, to changing accomplishments internally and externally, so that the plan is flexible and reactive.

VON ESCHENBACH: There are a couple of issues in that regard, one of which is, we have committed to an ongoing strategic planning process. We are not writing a strategic plan. I don't believe in plans that you then put on a shelf. What we are committed to is a planning process. We are committed to a schedule, for example, every quarter, we have one full day set aside where we meet as a strategic planning body to look at process.

Our mantra is: we get ready, we fire, and we steer. It's not: ready, aim, fire. It's ready, fire. We are launching. We are moving initiatives ahead that we believe are important strategically to impact on that continuum of cancer process. Strategies having to do with expansion of our early detection opportunities, using the opportunities that proteomics presents to us. Strategies having to do with looking at the metastatic phenotype as the lethal phenotype of cancer that provides great opportunities for us, if we begin to emphasize our understanding of tumor-host micro-environmental interactions, and relationships that exist in the metastatic phenotype and the role that micro-environment plays in that.

My point is, John, that we set out strategies. We look at them from the point of view of their impact on our achievement of the goal. Then, we monitor and steer as we track over time the impact of those strategies, the new opportunities that are becoming available and opportune to us in new areas that we can embark upon, for example, one of those being a very important effort right now to explore the impact of nanotechnology, and that's an initiative that Dr. Barker is heading up.

Our formula is a commitment, a mindset, a process that enables us to manage this portfolio on an ongoing basis to make sure that our investments

are wise and appropriate, given what's in fact occurring within the environment, and that we are moving those investments appropriately from completion to opportunity, constantly trying to move an entire agenda towards the goal of seeing a decline in burden of cancer, decline in death rates, prolongation of survival, and diminishing of suffering.

LARRY NORTON [NCAB member, director of medical breast oncology, Memorial Sloan-Kettering Cancer Center]: First of all, I applaud this goal. I think it's an extraordinary achievement just to state it with the boldness that you have. I also want to add that I agree that it's feasible. Largely, we have to remember the historic precedent, is that when we had truly major impacts on cancer, they sometimes occurred very quickly: gestational choriocarcinoma, pediatric leukemia, Hodgkin's, testicular. We have seen these in our own careers go from certainly fatal to high probability of cure, very rapidly with the introduction of new technologies, largely new drugs. I also applaud this focus on the kinetics of growth, which obviously I've dedicated a lot of my professional life to, because I think that's also a very important focus. Those are just comments. The question concerns this truly historic meeting you had at ASCO, not only the size of the room, which was historic in itself, but also because of the nature of the conversation, how candid it was, how open it was, and major issues you discussed with the FDA. One of the things that occurred to many in the room during that discussion is the relationship between industry, the private sector, and the public sector in this regard. We immediately left that session and then had all of our usual interactions with industry, which is very guarded, very careful. There is enormous screening of potentially useful compounds, many levels of screening before it gets up to phase I trials, based on the likelihood of success at the FDA, the likelihood the endpoints are accepted, in terms of traditional endpoints, and even marketing considerations, in terms of the number of patients who could benefit, the likelihood of producing the product. That seems to be emerging as one of the hurdles we are going to have to deal with. I'm wondering, from the NCI perspective, what your thinking is in that regard?

VON ESCHENBACH: I agree with you that, again, going back to the concept of a systems problem is going to require a systems solution, but that's a very important element of it. The current effort is the NCI and the FDA to work collaboratively first to effectively support each other in our individual missions. That's not occurring in a vacuum, either. I'm aware of a parallel effort that's occurring among the pharmaceutical and will include and reach out to the biotechnology arena, where they are looking at opportunities and models in which they can come together more effectively so that they don't impair their progress by unnecessary conflict. The model that's being looked at as a potential prototype as to how that could occur was the model that was developed when the semiconductor industry was faced with the same problems and the same challenges. They were working in independent silos and pursuing their independent agendas, and their ability to achieve those goals was hampered or undermined, because they couldn't achieve critical mass. Whereas, there was tremendous progress that was being made outside of this country by the Japanese. The semiconductor industry came together around a model called Sematech, which enabled them to create an entity where they could pool resources in a pre-competitive way, that developed infrastructure that they could all benefit from and use to propel their own individual initiatives….

They are looking at that. It may not work. But I'm aware of the fact that they are recognizing the same thing that the cancer community is recognizing, and that is, for us to achieve our goal, we are going to get their much faster working together than not. That's not easy to do, but at least there is a very significant awareness that that's got to be our reference. The genome project is a prime example of that proof of principle…. That proof of principle is being appreciated across the spectrum.

I'm not being Pollyannaish about this and underestimating the complexity or the enormity of the challenge, but I am absolutely convinced that it is within our grasp and is doable.

ELMER HUERTA [NCAB member, director, Cancer Risk Assessment and Screening Center, Washington Cancer Institute]: My comment has to do with a possible confusion that may arise. I got an email some time ago from a cancer survivor whose wife died of cancer. He told me he was really alarmed that the new goal of the NCI was to convert cancer to a disease that you can die with, not due to. He said, "Is it true that NCI doesn't want to pursue a cure for cancer? Are they changing their minds or philosophy?" The American Cancer Society asked the Gallup Organization to ask [people] what do you think is the primary objective of the society? Forty percent of people said they want the American

Cancer Society to find a cure for cancer. Forty-three percent said the first priority for the American Cancer Society should be to find a cure for cancer. So, it seems to me that we don't know how to explain this to the public, we don't know how to mobilize our PR, communications, we are going to find a misunderstanding from the public. I think the public has the right to hear from us. They think that we should find the cure, and if that's not the case, if your definition of cure is changing, we should explain that to them.

VON ESCHENBACH: I don't think there's any question that you are right. First of all, I think we have become aware in the cancer community that there is no magic bullet. Having said that, I do think, we are looking at it from the point of view of a disease which can be managed, as well as eliminated. I'm not backing off the fact that we will not eliminate cancer for many, if not most, patients, but I don't believe that's our only goal. I think we can also look at cancer as a disease that can not only eliminate, but a disease that we can manage. Much like we manage diabetes, much like we manage hypertension. We don't propose to patients that there is a cure for diabetes or there is a cure for hypertension. But we do propose to them that if they engage in appropriate management of the disease, it will not present any biologic threat to them. So, I think we have a challenge with the American people to help them understand, and have to understand their role and participation in the cancer problem. They are not passive in this. They have an active part in the equation. We are making the commitment to communications. We are making a commitment through Bob Croyle [director of the NCI Division of Cancer Control and Population Sciences] and some relationships we are developing, to be conscious of not only what it is we have to do, but recognizing always that the patient is the focus of what we are doing, and the patient is an active component of what we are doing, including helping the patient to understand. That's true of understanding the difference between curing cancer, or eliminating the suffering and death due to the disease….

JAMES ARMITAGE [NCAB member, dean, University of Nebraska College of Medicine]: Anytime you set out to achieve an important, exciting goal like this, there can be bumps in the road. I'm interested in what you think are the biggest threats to achieving the goal you set out. I can imagine them being things like, cancer turns out to be more of a moving target than we understand today, in some way analogous to infectious disease, or a huge scientific problem we never anticipated that we run into, or maybe more likely, the economy or Congress aren't as sympathetic and resources are not available to do what we need to do. What do you think are the biggest threats to your goal?

VON ESCHENBACH: Sometimes I see biggest threats and biggest opportunities as being mirror images of the same thing. Clearly, I think the whole problem of 9/11, and the whole need to begin to acquire a significant focus in our health care agenda to infectious disease and the problem of bioterrorism could be looked upon as a threat to the allocation of resources to solving the problem of cancer. I actually don't see it that way. I think we can turn that into a real opportunity, because as we are working in cooperation with NIAID and Tony Fauci on vaccine development, I think much of what is occurring in our expansion of that area of research can be integrated and coordinated with things that are appropriate for cancer. I think we are seeing a broadening. I alluded to the fact that our budget increases are not occurring at the double-digit level that they were before. I think that we have to partner and find other opportunities in those other places where strategic investments are being made.

The second thing I think is a real potential bump in the road is if we are unable to link to the issue of emerging complementary technologies. Bioinformatics and computational sciences, for example, are one of those areas where we can't create that intellectual capital in our own domain. We need to find ways to import that from other sectors where it's being developed. There are many strategic investments in that area being made in the intelligence community and the military, because of their needs. We have to find ways to not duplicate, but be able to integrate.

Bumps in the road will be if we can't make connections, if we can't access, and work in a way that we can import things that we can't make or can't do or can't create ourselves because we don't have the resources or the expertise within our own biomedical research community.

NIEDERHUBER: Andy, I want to thank you on behalf of the board for this candid and exciting and informative presentation and response to questions. I think all of us, have you have heard, accept the challenge of working with you toward the successful achievement of these initiatives, and of this ambitious, but much needed goal. We are with

you, we are behind you, we are committed to helping you.

VON ESCHENBACH: I am very grateful for the interaction. I think this has been a very important opportunity to interact with the board. I do appreciate your questions. The last time I presented this, you were, I think, more stunned. That's why I wanted to bring it back so that we did have the opportunity for discussion. I'm very appreciative of the direction you are providing to me and the NCI, and that the wider community is providing. This is a ready, fire, steer process. Steering has to come from the kind of input and appropriate, critical input that you and the rest of the community are providing. I welcome it. I welcome critical input. It will help us, not hurt us.

In Congress:

Feinstein Introduces Version 2 Of New National Cancer Act

Sen. Dianne Feinstein is making another attempt to change the fundamental legislation of the National Cancer Program.

The California Democrat has revised and reintroduced a bill that describes the vision of the new cancer program that emerged from the National Dialogue on Cancer, an initiative launched by the American Cancer Society.

An earlier version of the sweeping legislation, which stressed public health measures and proposed that FDA be given the authority to regulate tobacco, attracted 28 cosponsors in the 107th Congress and died in committees.

The second, scaled-down version of the bill, S. 1101, was introduced May 21. Though few observers expect the bill to pass in the 108th Congress, the legislation is significant because it can be presumed to mirror the strategies of the NCI leadership. The bill has 24 cosponsors.

Feinstein is the vice-chairman of the Dialogue. One of the Dialogue founders, Andrew von Eschenbach, now heads NCI. Another top Institute official, Anna Barker, deputy director for strategic scientific initiatives, served as a member of a Dialogue offshoot group that helped Feinstein develop the legislation. Von Eschenbach and Barker serve on the Dialogue steering committee (**The Cancer Letter**, May 30).

"I believe that if we work smart, we could find a cure for cancer in my lifetime," Feinstein said, introducing the bill. "I am the vice-chair of the National Dialogue on Cancer—and in discussions with cancer experts from this group, it became clear to me that the National Cancer Act of 1971 was out of date. We are now in the genomic era, on the cusp of discoveries and cures that we could only have dreamed about in 1971."

Version 2 of the Feinstein bill differs significantly from Version 1.

—The bill no longer calls for giving FDA the authority to regulate tobacco products.

—While Version 1 called for continuation of steep increases for NCI, Version 2 draws on two non-binding "Sense of the Senate" resolutions, one of which calls for NCI funding at the level of the bypass budget.

Introducing the bill, Feinstein said she pared it down in order to make it viable in the 108th Congress.

"What I have tried to do is take the most important components, in light of the current budget situation, and develop a piece of legislation that could pass the Senate," Feinstein said.

Version 2 includes the following new features:

—Reforming FDA. The bill directs FDA to develop a "strategic plan" for accelerating the process for reviewing cancer therapies.

In recent years, FDA has been breaking its own speed records in approval of cancer drugs, and data indicate that the number of applications in several areas, including cancer, has been dropping.

FDA is emerging as a gatekeeper in many of the measures the NCI Director von Eschenbach intends to carry out in his plan to end "suffering and death from cancer" by 2015 (**The Cancer Letter**, June 6).

In another far-reaching change for FDA, the Feinstein bill would amend the Orphan Drug laws to include therapies for "targets and mechanisms of pathogenesis of diseases."

The Orphan Drug law provides longer market exclusivity and stronger protection from competition for therapies intended for diseases that affect fewer than 200,000 people in the U.S. Currently, the Orphan Drug law is applied on the basis of "disease or condition," not molecular targets.

The bill does not appear to reflect the NCI push to recognize the surrogate marker of "intraepithelial neoplasia" as an endpoint for approval of chemoprevention agents (**The Cancer Letter**, May 30).

—Special Grants for Targeted Drugs. The NCI director would "carry out a research grant

program to provide funding to projects that seek to develop cancer treatments that target cancer cells."

The director would "award grants and facilitate the process to award grants to public or nonprofit private entities to conduct research to develop a molecularly-oriented, knowledge-based approach to cancer drug discovery and development," the bill states.

NCI would have to develop a strategic plan for development of targeted therapies. The bill authorizes $20 million a year for this research.

—**Patient Navigators.** The bill creates a demonstration program run through the Health Resources and Services Administration that would designate "patient navigators" to assist uninsured cancer patients in gaining access to health insurance and treatment, make appointments for follow up and referrals, and translate medical terminology.

—**Cancer Survivorship.** Under the legislation, the NCI Office on Cancer Survivorship would be headed by an associate director, who would work with other agencies involved in survivorship research.

—**State Cancer Registries.** The bill would allow the Centers for Disease Control and Prevention to make grants to state cancer registries "to monitor and evaluate quality cancer care, develop information concerning quality cancer care, and monitor cancer survivorship."

The determination of quality of care, one of the most challenging problems in cancer care, would be entrusted to panels convened by the Agency for Healthcare Research and Quality.

These panels would include "cancer experts, providers, patients, representatives of disparity populations, and other relevant experts, including representatives of the Institute, the Health Resources Administration and CDC."

The panels would develop "consensus protocols and practice guidelines for optimal cancer treatments and prevention, including palliation, symptom management, and end-of-life care."

As the preceding bill, the new version describes "translational cancer centers" as the principal pillar of the Feinstein approach to cancer research and cancer care.

The bill describes a "national network of at least 20 existing or new translational cancer research centers to conduct translational, multidisciplinary cancer research." These translational centers would have the authorized budget of $100 million a year.

They would perform the following functions:

—"Perform research for discovery and preclinical evaluation of drugs, biologics, devices, technologies, and strategies with potential to improve the prevention, detection, diagnosis, and treatment of cancer and to improve pain and symptom management and quality of life of cancer patients;

—"Perform clinical research studies on promising cancer treatments or strategies, in appropriate human populations;

—"Evaluate promising cancer diagnostic tests, techniques, or technologies in individuals being evaluated for the presence of cancer;

—"Perform all phases of clinical trials of new drugs, devices, biologics, or other strategies for treating patients with cancer, in collaboration with the existing NCI Cooperative Groups;

—"Develop and implement a plan to ensure the availability of adequate sources of patients for each type of clinical research study;

—"Create systems and external relationships, which do not duplicate capabilities available in the private sector, to accelerate the findings from translational research to a stage that private companies can assume development and commercialization; and

—"Develop and implement a plan expanding and disseminating the efficacious products of translational research to providers of cancer care, including products approved by FDA."

Letter To The Editor:

New Medicare Policy May Delay, Block Access To Cancer Drugs

To the Editor:

The far-ranging and thought-provoking discussion of Iressa's recent approval (**The Cancer Letter**, May 9, Vol. 29 No. 19) calls for clarification of several points.

First, the new coverage procedures being employed by Medicare are not applicable to Iressa because, as an oral self-administered drug, it is excluded from coverage by statute. The Access to Cancer Therapies Act (HR 1288, S1037) would correct this situation by extending Medicare coverage to all oral anti-cancer drugs. The legislation has the strong support of both the American Society of Clinical Oncology and the Cancer Leadership Council.

Second, the coverage procedures have been amended to delete "marketing approval based on the

use of surrogate outcomes" from the list of reasons a coverage determination might be undertaken for new drugs (68 Federal Register at 6637, Feb. 10, 2003). ASCO and the CLC strongly opposed the new coverage procedures as inconsistent with the Medicare statute, which requires coverage not only of the drug indications approved by FDA, but also medically appropriate indications that have not received FDA approval. Despite the amendment, Medicare coverage policy remains highly problematic as the remaining criteria for initiation of a coverage determination include findings that a new drug is "novel, complex or controversial" or "costly to the Medicare program." If the policy is not withdrawn, it is likely that access to many new cancer drugs will be delayed, if not denied outright, for Medicare beneficiaries.

Joseph Bailes
Executive Vice President
U.S. Oncology Inc.

The Cancer Letter Recognized For Coverage Of ImClone

Paul Goldberg, editor of The Cancer Letter, earlier this week received the Robert D. G. Lewis Watchdog Award from the Washington Professional Chapter of the Society of Professional Journalists for his coverage last year of ImClone Systems Inc. and its development of Erbitux.

Goldberg broke the story that FDA's "refusal to file" letter to ImClone indicated that problems with clinical trials of Erbitux were far more extensive than the company acknowledged (**The Cancer Letter**, Jan. 4, 2002). The story led to investigations by a Congressional committee and the Securities and Exchange Commission.

This is the second time Goldberg received the Lewis Award. He won previously in 1999. The award, which includes a $500 stipend, is given annually for the "best example of journalism aimed at protecting the public from abuses by those who would betray the public trust."

Goldberg's coverage of the ImClone controversy also received a first-place Washington Dateline Award from the SPJ chapter for newsletter reporting from Washington "that contributes to a better understanding of the federal government."

Earlier this month, Goldberg received an award for investigative reporting from the Newsletter and Electronic Publishers Foundation.

In Brief:

Caligiuri To Direct OSU Center, Succeeding Clara Bloomfield

(Continued from page 1)

Center, effective July 1, said **Fred Sanfilippo**, senior vice president for health sciences and dean of the College of Medicine and Public Health. Caligiuri will work with **David Schuller**, executive director of The Arthur G. James Cancer Hospital and Richard J. Solove Research Institute. He succeeds **Clara Bloomfield**, who has been the center director since 1997. Bloomfield will become the charter member of the new OSU Cancer Scholars Program, designed to recruit and retain senior cancer investigators with international stature. . . . **SAMUEL WAKSAL** was sentenced to seven years and three months and ordered to pay $4.3 million in fines and taxes in connection with trading of the stock of **ImClone Systems Inc.**, the company he founded. Waksal was sentenced June 10, and is scheduled to report to prison July 2. Waksal's friend and ImClone shareholder **Martha Stewart** was indicted on charges of securities fraud, obstruction of justice and conspiracy June 4. She pleaded not guilty. . . . **RICHARD PAZDUR**, director of the FDA Division of Oncology Drug Products, received the National Humanitarian Healthcare Award from the National Patient Advocate Foundation on June 6 "in recognition of outstanding leadership and steadfast commitment to improving patient access to quality healthcare." . . . **DANIEL VON HOFF**, professor of medicine and director of the Arizona Cancer Center, was awarded the Herbert J. Block Memorial Lectureship from the Arthur G. James Cancer Hospital and Richard J. Solove Research Institute at Ohio State University. He also will be the guest lecturer at the Andrew H. Weinberg Symposium at the Dana-Farber Cancer Institute. . . . **FRANK MEYSKENS**, director of the Chao Family Cancer Center and associate dean of research, College of Medicine, University of California, Irvine, will deliver the first Sydney E. Salmon Lectureship in Translational Research at the Arizona Cancer Center. . . . **CHRISTIANA CARE Health** System's Helen F. Graham Cancer Center of Wilmington, Del., received a $750,000 grant from AstraZeneca for a lung cancer prevention and early detection program. **Nicholas Petrelli** is medical director of the center, which opened last May. . . . **NEW YORK UNIVERSITY** Cancer Institute made two appointments. **Nina Bhardwaj** was named

director, Tumor Vaccine Program. She is professor of medicine, pathology, and dermatology at NYU School of Medicine. **Brian Dynlacht** was appointed associate professor and director of the Genomics Program. He was associate professor, Department of Molecular and Cellular Biology, Harvard University. . . . **CENTRAL BRAIN Tumor Registry** of the U.S., a non-profit statistical research organization, made its latest statistical report, "Primary Brain Tumors in the United States, 1995-1999," available at www.cbtrus.org. CBTRUS provides population-based incidence rates for all primary brain tumors since 1995. Funding comes from the Pediatric Brain Tumor Foundation of the U.S., the American Brain Tumor Association, the Children's Brain Tumor Foundation, National Brain Tumor Foundation, and NeoPharm Inc. CBTRUS is also under contract to the NCI Division of Cancer Control and Populations Sciences. . . . **UNIVERSITY OF PITTSBURGH**, in collaboration with Family Hospice and Palliative Care, has established The Institute to Enhance Palliative Care, a community of scholars and health professionals from diverse fields who are collaborating to improve end-of-life care, said **David Barnard**, institute director, professor of medicine and director of palliative care education, University of Pittsburgh Center for Bioethics and Health Law. . . . **ASCO Grants Program** awarded more than $3.6 million to cancer researchers, said **George Wilding**, chairman of the grant selection committee. The 14 recipients of the Career Development Awards received three-year grants for a total of $170,000. ASCO awarded 35 Young Investigator Awards, one-year grants of $35,000, and 100 Merit Awards of $1,500 travel assistance to attend the annual meeting. . . . **RICHARD PARIS** was appointed vice president for human resources at Roswell Park Cancer Institute. He was vice president for human resources at the Children's National Medical Center in Washington, D.C. . . . **RONALD HOFFMAN**, director of the Cancer Center at the University of Illinois at Chicago, has been elected president of the American Society of Hematology. . . . **PEDIATRIC BRAIN TUMOR Foundation Institute** at Duke Comprehensive Cancer Center was established with a $6 million award from the Pediatric Brain Tumor Foundation. The goal of the institute will be to develop less-invasive clinical treatments for children diagnosed with brain tumors. **Darell Bigner**, deputy director of the cancer center, was named director of the institute.

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