THE CANCER LETTER

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Conversation with The Cancer Letter

Ending Breast Cancer by 2020? NBCC's Visco Discusses the Goal

Two years ago, the National Breast Cancer Coalition set the deadline to end breast cancer by Jan. 1, 2020. The Cancer Letter invited NBCC President Fran Visco to talk about pursuing this goal. Visco spoke with The Cancer Letter editor Paul Goldberg. To hear the conversation, follow this link.

PG: *It's been more than two years since you set the 2020 deadline to end breast cancer. Recently, an editorial in Nature criticized this plan saying, "Discovery does not answer to deadlines, and campaigns that pretend that it does risk wasting public trust." What do you say to that?*

FV: Well, I thought it was a very interesting statement for them to make.

On one level, I think we were pretty impressed with the fact that Nature actually wrote about the deadline campaign. And we've had a lot of feedback from scientists saying it was a good thing.

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NCI Cancer Bulletin, 2004-2012

NCI Gets Out of the News Business

By Paul Goldberg

After nine years and millions of dollars, the NCI venture into journalism has ceased publication.

The decision to end the NCI Cancer Bulletin is part of efforts by NCI Director Harold Varmus to knock down the costly remnants of pet projects inherited from his predecessors.

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In Brief

Kurzrock and Ferrara Join UCSD Moores Center

RAZELLE KURZROCK and **NAPOLEONE FERRARA** have officially joined the **University of California San Diego Moores Cancer Center**.

Kurzrock is the senior deputy director for clinical science and comes from MD Anderson Cancer Center, where she developed a phase I clinical trials program that emphasized personalized medicine.

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Von Eschenbach's 2015 Goal "Haunts" Every Goal Set Since

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At the same time, I was pretty surprised that Nature would spend the time criticizing a patient advocacy group—especially one like ours that has spent 20 years fighting for support for science and collaborating with scientists—and that they would spend their time attacking us rather than attacking some of the pretty egregious problems in science at the moment.

But given all of that, I felt that their statement that science doesn't respond to deadlines was unfortunate. Because I don't know if we can end breast cancer by 2020 or 2030—we've never tried to do that. We've never set a deadline for breast cancer and tried.

I've always been a bit of a science geek, and I've always been so impressed with science and scientists, so what I thought what they were about was asking really big questions and challenging what people believed to be the case—fighting against the status quo and being creative and innovating and taking on really big challenges—and that's what this is.

So I was sad, in a way, that the scientists at Nature took that approach. It's unfortunate. I think it's also endemic of the problems that we face in science at the moment—scientists being worried about taking those big ideas somewhere and just focusing on how they can get their next grant—not all scientists, but too many of them. And I think that's what was reflected in the Nature editorial.

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PG: *We talked about this when you first set the deadline* (The Cancer Letter, Sept. 24, 2012)*, this would be more than two years ago—is it really a deadline, or is it a promise?*

FV: We look at it as a deadline.

We set a deadline, and by 2020 we want to know how to end breast cancer. We understand that on Jan. 2, 2020, there is no way there will be no more breast cancer anywhere. There are so many access issues and so many difficult issues that need to be addressed.

We do believe strongly that this is a deadline. We are not making a promise. No single institution or single agency or single individual can make a promise. We are setting a deadline and we are leading a movement. We are leading a campaign and we are collaborating with scientists and leaders at every level to achieve that deadline. That's our goal and that is what we're going to do.

PG: *So who is working with you on this? Are other scientists collaborating on this?*

FV: There are a number of scientists who are collaborating with us. When Nature was concerned about the public trust—and I think the public does trust when scientists collaborate with advocates to try and answer the big questions and try to save lives.

I think that the public's trust in science and their support for science erodes when there are scientific flaws, such as when results can't be replicated, when not enough is translated to actually help people—where the focus is on refining tools and technology rather than applying them.

I think there are many ways in which we can lose the public's trust, but the fact that we're collaborating with scientists to try and end breast cancer…I don't think that's going to do it. I think the public would be very happy about that.

When we first launched the deadline, I put the scientific response into three buckets. One bucket was, "Well, I don't know if we can do this, but let's try. We need to try, let's work together to try."

And then we had scientists who said there's absolutely no way that can happen. We sat down with as many of those scientists as we could to say, "Tell us why what do you see as the barriers, maybe we can work together to overcome those barriers."

And then there was a group of scientists who lashed out and said, "You are just attacking us. You are telling us that what we're doing isn't good enough." And as far as I'm concerned those scientists weren't really going to help anyway.

So those were the three categories. We do have a

category of people who are working with us in a positive way to move forward on, for example, the Artemis project for a preventive vaccine and the work that we're doing in metastasis.

And the other group of scientists that do not believe that it is possible, some of them are helping us identify what the barriers are that they see, and what the strategies are that we can use to overcome those barriers.

PG: *Is there a list or is there a place to find out who's doing what?*

FV: Well if you go to our website, www.breastcancerdeadline2020.org, you'll see information on our Artemis Project, for example.

We've been very accountable and transparent about the work that we're doing, and you'll see the summit reports from our primary prevention in preventing metastasis summits. You'll see the reports of the work that we've been doing on the preventive vaccine, and all of those reports have lists of the scientists that participated.

PG: *Is there money?*

FV: We are not an organization that gives out money to scientists.

It's very funny, when we started with the campaign, and talked about how we need to build an infrastructure for collaboration in order to address big questions, a lot of people said to us—even within the advocacy community—how are you going to get scientists to work with you when you are not writing them big checks?

I have a lot more faith in scientists than that, I think there are many scientists who want to do the right thing.

PG: *So they get their funding elsewhere?*

FV: They get their funding elsewhere.

We had some money for seed grants that we give out through the national philanthropic trust. So we're not talking big dollar—but so far we've given out two seed grants for the preventive vaccine work. We'll be giving out some metastatic seed grants over the next six to eight months.

PG: *Is there a difference between a bureaucrat setting a deadline, like for example [former NCI Director] Andrew von Eschenbach, and an advocacy group setting a deadline? I actually think that there is. How would you define that difference if you agree?*

FV: Well, I think that there is a difference on a number of different levels, but one of the differences is when any one institution or agency sets a deadline, it makes it very difficult to be taken seriously.

For a patient advocacy group it's a bit different. We have one agenda. Our agenda is to end breast cancer. We are not beholden to any institution; we are not beholden to Congress or the White House. We are beholden to women globally and making certain that no one dies of breast cancer.

So we have an ability to be very broad-based about what it is we do—our hands are not tied.

In addition, we don't have the regulation that something like the NCI has from Congress, and the restrictions that they have. They're there to help give out money and to help set an agenda across all cancers.

We are here to end breast cancer—it's a very different mission, a different goal. And we're able to do it in a way that a bureaucracy and a bureaucrat cannot. Our hands are not tied in the same way.

PG: *I guess the bigger question is the question of somebody a the position of authority who is running a $5 billion institute saying, "We will ending suffering and death due to cancer in the year 2015," which has been done, it's very different from you saying, as an advocate, "I don't care what it costs, let's just do it."*

FV: Look, the man on the moon is the example that everyone gives.

When I first started 20 years ago, getting involved in science and advocacy—remember, this is not my world. I came into this world from a very different one. When I first got involved in it, I would hear people talk about the man on the moon—I thought that was naïve.

I thought, "We are not talking about the man on the moon, we are talking about biology and science and it's a very different thing." Now I've been doing this for 20 years—and I've seen so many different scientists and individuals and bandwagons in science—that now I don't think that it's naïve.

Now I think that, if you are able to focus on an issue and bring to bear all of the stakeholders and financial wherewithal that needs to be put there in order to achieve the goal, I think you can put a man on the moon. We've shown that. And I think you can end breast cancer.

We didn't have government leadership saying, "Let's end suffering and death due to cancer by 2015." I wonder often what would have happened if as similar an emphasis as there had been for man on the moon had been put behind Andy von Eschenbach's goal.

What would have happened?

PG: *Are you suggesting that you're in agreement with that goal, and that not enough money was put into it?*

FV: Oh, I don't think it's just money. It's never just about money. It's always about leadership, and strategy, and approach, and I think you have to set big goals.

You have to have big ideas, otherwise you are

just asking the question about what's the next pathway we should look at in breast cancer, or how we should get more women screened rather than fewer women screened.

You are looking at very small questions and that keeps the breast cancer infrastructure going, it keeps the business going—but it not going to get us to the place where we're saving more lives, where we're really ending the disease.

You need to take on big challenges to do that. I'm sorry Andy von Eschenbach set that goal—not because he didn't reach it—I'm sorry he said it, because it's sort of haunting every other goal that's been set.

There's a goal in diabetes, there's a goal in Alzheimer's—and I hope everybody finds a way to achieve their goals—but we're never going to unless we set the goal to begin with.

We feel that we are doing this in a very collaborative way. We're doing it in a way that has attracted some of the best scientists. We are doing it in a way that is allowing science to thrive in a creative and innovative environment. And I think that we are taking the right approach and the right strategy.

Our strategy is not "if we only give scientists more money, they will answer the question." The way to do this is to really be strategic, to really figure out what the mission is and how to get there by working together.

And that is exactly what we are doing.

PG: *But you do understand the poor karma, the really bad karma of deadlines…*

FV: Here's what I think:

I'm an activist, and as an activist I set a big goal and I figure out how to get there.

Everyone can be poking me and pushing me and saying, bad karma in deadlines, Andy couldn't do it, this is ridiculous—you can push and poke all you want. I. Don't. Care.

I need to keep my eyes focused on that mission and I need to figure out how to get there.

And that's exactly what we are doing. There's always going to be people—and there should be people saying that it's not possible, because we need to figure out why they believe that and then figure out how to overcome that. And just saying that Andy set a goal and Andy didn't make it isn't evidence to me that you can never achieve a deadline.

PG: *Well, the concern that I've always had with something like this is you can't cure cancer by these deadlines, nobody has been able to do it up until now, but one could certainly get rid of the people—or persecute, really—the people who disagreed.*

But that's not a situation you can be in as an advocate, although in some ways you're getting some backlash on the goal right now.

FV: We always assumed we would get backlash—we are challenging the status quo.

We are trying to get people to do something very different; something outside of their comfort zone. Of course we are going to get backlash.

I think it's a good thing that we are getting backlash, again, because it allows us to change the conversation and to engage in dialogue and to figure out what are the barriers and challenges we have to overcome to achieve the mission.

PG: *You have to do this, in a sense, but you did this with your eyes open, I assume*

FV: Well we didn't have to do this, I'm not sure that's true.

Because when we looked at the world of breast cancer, we truly did ask the question: Alright, it's 20 years later, and the National Breast Cancer Coalition brought about incredible change—the Department of Defense program, an incredible amount of money for scientists, trained and educated advocates, collaborations, changes in clinical trials, expanding access to care—all of these things we have done, but the numbers, the statistics, they are not changing. Not in any way that is commensurate with the amount of investment in this issue and the years of focus on it.

And breast cancer is becoming a bigger and bigger business, with a bigger and bigger infrastructure, and I think a lot of the really important stuff is getting lost.

So we looked at all that and we said, Can we still make a difference? Is there still a place for the National Breast Cancer Coalition for this kind of advocacy? Because, trust me, all of the grassroots advocates who were part of the coalition have a lot of other things they could be doing.

So we said, should we walk away? Should we maintain the status quo? Or should we really focus on our mission?

We made the decision that we would either walk away or really focus on our mission—we had no interest in just trying to support the status quo. So in that way, this was something that we had to do.

PG: *So why 2020? And not 2019 or 2021?*

FV: Why not 2025 or 2030? We looked at what was possible. And we believed that given everything that had been invested to date, and all of the attention and the focus—the tools, the technology, the knowledge, the relationships that we had formed—we believed that it is possible to do it by 2020.

We could have said 2030 and given ourselves some time, but the urgency isn't there when you say 2030. We wanted to pick a date by which it was possible to do it—we knew it would be incredibly difficult, but it would be possible to do it—and still have a sense of urgency associated with it.

If we had said 2030, people would have waited seven, eight, nine years before they really got invested in us. We needed that urgency and that's why it was 2020.

PG: *As I read the Nature editorial, I see that it was really brought on by the fact that Bill Clinton is the 2020 campaign honorary chair. So, I guess, in a way, you were picked on because you are relevant politically. What's Bill Clinton's role in this, and why did he agree to play?*

FV: We've had a long-standing relationship with him at the beginning of his administration, with both Bill and Hillary Clinton, and we worked together very closely the years that he was in the White House, for a number of different breast cancer issues. His mother died of breast cancer when he was in the White House. It's a very important issue to him and to Hillary Clinton.

I believe that he signed on to it because he trusts that we are an organization that gets things done. We take on difficult issues and we want to challenge big ideas and we want to challenge big issues—and that is something that resonates with him. We understand that this is a global issue, and that resonates with him, too. And that's why we believe he signed on to be a part of this.

And as to what his role will be, the first thing that he is going to do is—we're working on putting together a global leadership committee meeting with no more than 40 individuals, leaders from around the globe who are stakeholders or leaders who could make a difference in this campaign, and bring them together, at his invitation, to look at the campaign and address some of the big issues and help develop the strategy more.

PG: *Is fundraising a part of it?*

FV: Of course, fundraising is a part of everything that we are doing. We do need significant funds to do the campaign, there's no question about that.

PG: *Do you know how much is needed?*

FV: Yes. We looked at the Artemis Project and the other projects that we are doing. and we need to raise a total of $150 million over the next remaining seven years of the campaign.

PG: *So you've been doing this for two years, and you have seven years left. Is the goal getting closer?*

FV: Well, I believe it's getting closer. The deadline is getting closer, and I believe our work is making a difference.

We are very excited about what we are doing with the preventive vaccine work, and also with the stopping metastasis work, and working at these issues in very different ways, and changing the conversation around breast cancer.

That is so important. If a conversation stops focusing on the next grant, and it stops focusing on screening and expanding mammograms for women around the world, and it really focuses on how we can end this disease, how we can stop women from dying, then that's an incredible contribution that we've made in the short term.

But that's where the conversation has to be.

PG: *What do you think is the most important lesson you've learned from this so far?*

FV: I don't think there is one most important lesson. I think that I've learned that—and I think a lot of the advocates would agree with me—that we've learned that there are many more scientists that are willing to be a part of this than there were at the beginning, and to some extent we underestimated they're willingness to take a chance with us to try and make this happen.

So that was one lesson that we learned, and, at the same time—this maybe sounds contradictory—we learned that the infrastructure and business of breast cancer is really rooted and very difficult to change. Even more difficult than we thought.

We've always thought we are on the periphery, making this work regardless, but now we have to do some chipping away at that infrastructure.

So those are the two out of many lessons I've learned.

PG: *How do you chip away at it?*

FV: You chip away at it by getting people like Bill Clinton to agree to be honorary chair, and by bringing credibility and visibility to the campaign by having scientists that are very well regarded speak about the deadline.

PG: *Who, out of the scientists, has done that?*

FV: I would say most of the scientists who are involved in our work in the deadline campaign have been speaking about it.

I've heard people talking about it that surprised me they even knew about it. I think the Nature editorial actually, to some extent, is helpful to spread the word about the campaign. But many of them are talking about it.

If you go on our website and see the list of individuals—especially those who were part of the preventive vaccine work, because that's the most mature of the work that we've been doing, because we

actually launched that before we launched the deadline campaign.

PG: *Well thank you very much.*

FV: You are welcome.

NBCC's, response to the Nature editorial, in the form in which it was submitted to the journal, is available on our website. The document's edited version was published Jan. 16.

NCI Cancer Bulletin, 2004-2012

NCI Gets Out of News Business

(Continued from page 1)

The demise of the Bulletin comes at a time when Varmus and the National Cancer Advisory Board are focusing on slashing the $45 million budget of the NCI Office of Communications and Education (The Cancer Letter, Dec. 7, 2012).

In addition to not being reviewed by any external advisory board, the Bulletin was never cleared by NIH staff, which typically reviews press releases and printed brochures published by institutes and centers.

The Bulletin began as one of the highest-profile projects launched by then-NCI Director Andrew von Eschenbach and was intended to provide support for his plan to "end suffering and death due to cancer" by 2015.

The first issue, in January 2004, focused on the exact same area of coverage as The Cancer Letter and was crafted to look remarkably like this publication, albeit with one the important distinction: the Bulletin featured a photo of von Eschenbach on the cover.

Indeed, according to an announcement by von Eschenbach, the Bulletin was going to provide "the most useful and authoritative news concerning important NCI programs and initiatives." It was intended to be the principal channel for the institute's communications with the outside world.

The Bulletin didn't limit its focus to NCI. It purported to cover all of cancer research, publishing tame stories about Capitol Hill, FDA, CDC and other agencies.

Internal NCI emails and memoranda obtained by The Cancer Letter under the Freedom of Information Act show that the institute intended to create the illusion that the Bulletin was, in fact, a bona fide independent news publication.

After von Eschenbach's departure, NCI abandoned the 2015 plan, and cut the Bulletin down to a biweekly schedule. In another setback, the Bulletin lost a key contributor when Varmus apparently declined to contribute the "Director's Update" feature.

Setbacks aside, the Bulletin continued, adding a Spanish-language version and aggressively seeking new readers, documents obtained by The Cancer Letter show.

Before it was shut down, its reported personnel and contractor costs exceeded $600,000 a year, enough money to fund two R01 grants.

It's not clear whether any of these costs will be recouped and redirected since most of this money paid for the at least four full-time federal employees who were engaged in producing the newsletter.

The demise of the Bulletin was announced to the institute staff in a memo from Jim Mathews, the newsletter's editor-in-chief.

The text of the email, dated Jan. 11, follows:

Dear EEC Members and DOC Communications Managers,

As some of you already know, earlier this week, the NCI OD directed that the NCI Cancer Bulletin and the Spanish-language Boletín online newsletters suspend publication until further notice so that their personnel can be reallocated to other OCE communications activities and priorities.

This decision was made as part of NCI's ongoing efforts to examine how best to apportion its limited resources. Staff currently assigned to the NCI Cancer Bulletin will, in the short term, continue to work and develop content while OCE leadership determines the best way to utilize their skills and experience to complement OCE's evolving role within the Institute.

As a consequence of this decision, it is no longer necessary for the NCI Cancer Bulletin Executive Editorial Committee to convene so the Feb. 7 meeting will be cancelled.

I would like to extend my sincere thanks to each of you for your time and commitment in advising and guiding us in the production of high-quality scientific news content for our readers. I especially want to thank the DOC communications managers—particularly those who have been working with us since the newsletter was launched over 9 years ago. We look forward to continuing our working relationship in other ways and through other communications endeavors.

In the meantime, if you have any questions please don't hesitate to contact me or EEC Chair Dr. Rick Manrow.

Thank you,
Jim Mathews

Next week: NCI's costly effort to create an official news organization, a story based on 1,459 pages of internal documents.

Smoking and Cancer

Study: "If Women Smoke Like Men, They Will Die Like Men"

Female smokers have a much greater risk of death from lung cancer and chronic obstructive lung disease in recent years than female smokers 20 or 40 years ago, reflecting changes in smoking behavior according to an article published in New England Journal of Medicine.

The increase has been large enough to completely offset improvements in longevity from medical advances that have reduced death rates in the rest of the population over the last 50 years.

Female smokers today smoke more like men than women in previous generations, beginning earlier in adolescence and, until recently, smoking more cigarettes per day. Consumption peaked among female smokers in the 1980s.

To find out if these changing patterns have caused women's risk to converge with those in men, researchers measured 50-year trends in mortality related to smoking across three time periods—1959 to 1965, 1982 to 1988, and 2000 to 2010—by comparing five large contemporary studies with two historical cohorts from the American Cancer Society. The study included more than 2.2 million adults 55 years and older.

For women who smoked in the 1960s, the risk of dying from lung cancer was 2.7 times higher than that of never-smokers. In the 2000-2010 cohort, the risk was 25.7 times higher than that of never-smokers.

The risk of dying from chronic obstructive lung disease among female smokers was 4.0 times higher than that of never-smokers in the 1960s; in the contemporary cohort, this risk increased to 22.5 times higher than never-smokers. About half of the increase in risk of both conditions occurred during the last 20 years.

In male smokers, lung cancer risk plateaued at the high level observed in the 1980s, while the risk of death from chronic obstructive lung disease continues to increase for reasons that are unclear.

Men and women smokers in the contemporary cohorts had nearly identically higher relative risks, compared to never smokers, for lung cancer, chronic obstructive lung disease, ischemic heart disease, stroke, and other heart disease.

This finding strongly confirms the observed prediction that "if women smoke like men, they will die like men."

The research also confirmed that quitting smoking at any age dramatically lowers mortality from all major diseases caused by smoking, and that quitting smoking is far more effective than reducing the number of cigarettes smoked.

The study found smokers who quit by age 40 avoided nearly all of the excess smoking-related mortality from lung cancer and COPD.

"Act I in this tragedy was the epidemic of cancers and other smoking-related deaths among men in rich countries," said Michael Thun, who recently retired as vice president emeritus of the American Cancer Society. "Act II is the same story in women. And now we're right on track for Act III, the global epidemic from smoking in developing countries."

"The steep increase in risk among female smokers has continued for decades after the serious health risks from smoking were well established, and despite the fact that women predominantly smoked cigarette brands marketed as lower in tar and nicotine," said Thun.

"The findings from these studies have profound implications for many developing countries where cigarette smoking has become entrenched more recently than in the U.S.," said Thun. "Together they show that the epidemic of disease and death caused by cigarette smoking increases progressively over many decades, peaking fifty or more years after the widespread uptake of smoking in adolescence. The good news is the benefits of smoking cessation occur much more quickly and are substantial at any age."

Cancer Facts & Figures

Cancer Mortality Down 20 Percent Avoiding Nearly 1.2 Million Deaths

As of 2009, the overall death rate for cancer in the U.S. had declined 20 percent from its peak in 1991, avoiding approximately 1.2 million deaths from cancer. These figures come from the American Cancer Society's annual cancer statistics report.

The report—Cancer Facts & Figures 2013; and its companion article Cancer Statistics 2013, which was published in CA: A Cancer Journal for Clinicians—compiled information on cancer incidence, mortality, and survival based on incidence data from NCI and the Centers for Disease Control and Prevention, and mortality data from the National Center for Health Statistics.

The report said that 152,900 deaths were avoided in 2009 alone. According to the study, a total of 1,660,290 new cancer cases and 580,350 cancer deaths are projected to occur in the U.S. in 2013.

Cancer death rates decreased from their peak of 215.1 per 100,000 in 1991 to 173.1 per 100,000 in 2009.

Death rates continue to decline for all four major cancer sites: lung, colon and rectum, breast, and prostate.

Over the past two decades, death rates have decreased from their peak by more than 30 percent for cancers of the colorectum, female breast, and male lung, and by more than 40 percent for prostate cancer. These large drops are primarily due to reductions in smoking for lung cancer and to improvements in early detection and treatment for colorectal, breast, and prostate cancers.

Among men, cancers of the prostate, lung and bronchus, and colorectum will account for half of all newly diagnosed cancers; prostate cancer alone will account for 28 percent (238,590) of incident cases in men. Among women, the three most commonly diagnosed types of cancer in 2013 will be breast, lung and bronchus, and colorectum, accounting for about half of all cases. Breast cancer alone is expected to account for 29 percent (232,340) of all new cancer cases among women.

While incidence rates are declining for most cancer sites, they are increasing among both men and women for melanoma of the skin and cancers of the liver, thyroid, and pancreas. Overall cancer incidence rates decreased slightly in males (by 0.6 percent per year) and were stable in females in the most recent five year period for which there is data (2005-2009).

Cancers of the lung and bronchus, prostate, and colorectum in men and cancers of the lung and bronchus, breast, and colorectum in women continue to be the most common causes of cancer death. These four cancers account for almost half of the total cancer deaths among men and women. In 2013, lung cancer is expected to account for 26 percent of all female cancer deaths and 28 percent of all male cancer deaths.

Cancer death rates decreased by 1.8 percent per year in males and by 1.5 percent per year in females during the most recent five years of data (2005-2009). These declines have been consistent since 2001 and 2002 in men and women, respectively, and are larger in magnitude than those occurring in the previous decade. Between 1990/1991 and 2009, cancer death rates decreased by 24 percent in men, 16 percent in women, and 20 percent overall.

In Brief

Kurzrock and Ferrara Join UCSD Moores Cancer Center

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In addition, Kurzrock will head Moores' new Center for Personalized Therapy. She is also vice chief of the Hematology-Oncology Division in the UC San Diego School of Medicine.

Ferrara joins Moores from Genentech, where he focused on treatments for cancer and age-related macular degeneration, based upon the discovery of growth factors that promote angiogenesis, including VEGF.

Ferrara serves as senior deputy director for basic science and is a distinguished professor of pathology in the UC San Diego School of Medicine.

ROBERT GAGEL will step down as division head of internal medicine at **MD Anderson Cancer Center**.

He will lead the division during the search for a replacement, after which he'll return to the Endocrine Neoplasia and Hormonal Disorders faculty, where he'll continue to serve as director of the Bone Disease Program of Texas, a collaborative clinical and research program between MD Anderson and Baylor College of Medicine.

A search committee will be formed in the next few weeks, MD Anderson officials said. Gagel will also continue his academic pursuits, centered on cancer diagnosis, treatment, and bone biology.

Gagel joined MD Anderson in 1991 to head the Section of Endocrine Neoplasia and Hormonal Disorders. In 1998, he was appointed chair of the Internal Medicine Specialties department. When Internal Medicine became a division in 2001, Gagel was named its founding division head.

During Gagel's tenure, the division has grown from 50 to 150. In its infancy, the division evaluated approximately 13 percent of all MD Anderson patients. Last year, the division was responsible for a quarter of all patient interactions.

Gagel's major research focus has been the biology and treatment of hereditary and sporadic medullary thyroid carcinoma.

Previously, Gagel and colleagues defined the role of prospective screening in the management of hereditary medullary thyroid carcinoma. His work helped define the importance of early identification of the disease. A 40-year follow-up study proved early intervention is curative.

FDA News

FDA Expands Gleevec Indication To Treat Children with Ph+ ALL

FDA approved a new use of **Gleevec (imatinib)** to treat children newly diagnosed with Philadelphia chromosome positive acute lymphoblastic leukemia. It should be used in combination with chemotherapy.

Gleevec's safety and effectiveness for this new indication were established in a clinical trial conducted by the Children's Oncology Group, sponsored by NCI. The trial enrolled children and young adults 1 year and older with very high risk ALL, defined as patients with a greater than 45 percent chance of experiencing complications from their disease within five years of treatment.

Ninety-two patients with Ph+ ALL were enrolled in the trial and divided into five treatment groups, with each successive group receiving a greater duration of Gleevec treatment in combination with chemotherapy.

Fifty of the Ph+ ALL patients received Gleevec for the longest duration, and 70 percent of these patients did not experience relapse or death within four years. Results also showed patient deaths decreased with increasing duration of Gleevec treatment in combination with chemotherapy.

The most common side effects observed in children with Ph+ ALL treated with Gleevec in combination with chemotherapy included decreased levels of infection-fighting blood cells called neutrophils; decreased levels of blood platelets, which assist in blood clotting; liver toxicity; and infection.

Gleevec is marketed by Novartis.

FDA approved a new use of **Avastin (bevacizumab)** in combination with fluoropyrimidine-based irinotecan or oxaliplatin chemotherapy for people with metastatic colorectal cancer.

The new indication will allow people who received Avastin plus an irinotecan or oxaliplatin containing chemotherapy as an initial treatment for mCRC to continue to receive Avastin plus a different irinotecan or oxaliplatin containing chemotherapy after their cancer worsens.

Avastin in combination with fluoropyrimidine-irinotecan or fluoropyrimidine-oxaliplatin based chemotherapy is now indicated for the second-line treatment of patients with metastatic colorectal cancer who have progressed on a first-line Avastin containing regimen.

The approval is based on positive results from the phase III ML18147 study, which showed that people who continued to receive an Avastin-based regimen after their cancer worsened lived longer than people who switched to chemotherapy alone.

The risk of death was reduced by 19 percent for people who received Avastin in combination with standard chemotherapy in both the first- and second-line compared to those who received chemotherapy alone (HR=0.81, p=0.0057). Median overall survival was 11.2 months compared to 9.8 months.

The risk of the cancer worsening or death was reduced by 32 percent (HR=0.68, p<0.0001). Median progression-free survival was 5.7 months compared to 4.1 months. Adverse events in were consistent with those seen in previous trials of Avastin in mCRC.

This is the third approval for Avastin in mCRC based on improved overall survival. Avastin is not indicated for adjuvant treatment of colon cancer. Avastin is sponsored by Genentech Inc.

FDA expanded the approved use of **Exjade (deferasirox)** to treat patients ages 10 years and older who have chronic iron overload resulting from non-transfusion-dependent thalassemia.

NTDT is a milder form of thalassemia that does not require individuals to get frequent red blood cell transfusions. However, over time, some patients with NTDT are still at risk for iron overload that can lead to damage to vital organs.

FDA is also authorizing marketing of **FerriScan** as an imaging companion diagnostic for Exjade. The agency previously cleared FerriScan for measuring liver iron concentration—but its use in Exjade clinical studies to select patients for therapy, and to manage therapy, defined its role as an imaging companion diagnostic necessary for Exjade's safe and effective use. FerriScan measures LIC non-invasively using magnetic resonance imaging.

Exjade was previously approved for treatment of chronic iron overload due to blood transfusions in patients ages 2 years and older, and this approval extends its use to treat patients with NTDT who show

iron overload. Exjade should be used in patients with NTDT who have an LIC of at least 5 milligrams of iron per gram of dry liver tissue weight.

Exjade's new indication is being approved under the FDA's accelerated approval program. Exjade was approved based on clinical data showing it can reduce LIC to less than 5 mg/g dry weight, a surrogate endpoint that is judged reasonably likely to predict a clinical benefit to patients.

The safety and effectiveness of Exjade to treat chronic iron overload in patients with NTDT were established in two clinical trials designed to measure the number of patients whose LIC was reduced to less than 5 mg/g dry weight after 52 weeks of treatment.

In the first trial, 166 patients were randomly assigned to receive 5 mg/kg of Exjade, 10 mg/kg of Exjade, or a placebo daily. Results showed 15 percent and 27 percent of Exjade-treated patients achieved the target LIC, respectively, compared with 4 percent in placebo-treated patients. The second trial contained 133 patients from the first study who received an additional year of Exjade treatment or switched from placebo to Exjade treatment. Thirty-five percent of the evaluable patients in this extension trial achieved the target LIC.

Exjade is marketed by Novartis. FerriScan is marketed by Resonance Health.

Letter to the Editor

The article on the new practice models being developed by Carolinas Healthcare was interesting, and I wish them well in their endeavor. We are in desperate need of revamping how we deliver healthcare, and specifically cancer care from lifestyle changes to other preventive strategies to screening to caring for our survivors and their families.

However, a statement in the article is a bit revisionist:

"Most of cancer care was deliberately taken out of hospitals and was provided by oncology practices. This system was created in the sixties and seventies in order to save money on administration of chemotherapy. To pay for equipment and work required to administer chemo, doctors were allowed to keep the 'spread' between the price at which they bought the drugs and the price that ended up on the patients' bills. For years, oncologists argued that they were underpaid for the services they provided, but the spread allowed some practices to generate considerable revenues."

I was one of the first community based oncologists in Maryland in 1977. There was no cancer care in any organized sense in many communities. The insurers didn't want to pay for it, and in fact there weren't any CPT codes for billing purposes. As a physician committed to providing high quality outpatient oncology care along the lines of what we did at the National Cancer Institute, I still recall a meeting when representatives from the local Blue Cross plan came to my office and asked me to admit my patients for a simple once a day 5FU injection since—as they told me directly—they didn't want a sicker, more expensive patient to occupy the bed. And, yes, we participated in clinical trials—including some phase I work, believe it or not—and took care of the indigent patients as well. We were even site-visited as part of our cooperative group work and received excellent reviews.

Oncology drug pricing started out as average wholesale price, which really was "average ***wholesale*** price" (emphasis mine). The difference between the AWP—which is what we were reimbursed by Medicare—and the actual retail costs of the drugs came out of our own pockets.

I once had to go to Congress to get Medicare to pay for etoposide for small-cell lung cancer, but it was FDA approved only for testicular cancer. The fact that at the time it was the single most effective drug to treat the disease made no difference to the Medicare folks. It wasn't FDA approved, so no reimbursement was available. Eventually, we prevailed but not without considerable effort.

Over time, the drug companies did reduce their prices substantially below AWP, but that didn't happen for several years. Our practice lost money on chemotherapy drugs. It was one of the reasons I eventually left oncology to go into primary care. The economics simply didn't work well, among other considerations.

So what we have today is certainly much different than what it was back then. I understand that. As to reimbursement, during deliberations several years ago at the RUC to adjust payments for chemotherapy services, we asked the oncologists to include all of the extra "unbillable" services they were reportedly providing with the differential monies they received between payments based on the then current version of "AWP" and actual cost of the medicines, but never got any evidence of same. So we couldn't include it in the reimbursement models when we concluded our deliberations. I still regret that we could not have done more to increase payments for chemotherapy services, given all of the actual work that occurs as part of cancer treatment.

Now, according to what I have been told by accurate sources, there are no truly private oncology practices in Massachusetts. In some states there is no longer any rural general medical oncology care. I made a prediction several years ago that the oncologists remaining in private practices will find themselves in the same predicament the gerontologists are in, where the patients are typically ill and complex, reimbursements for evaluation and management services don't cover the intensity of the service, and they have few procedures to make up the difference.

The health systems which are now so quick to purchase oncology practices are—in our new world order, where costs play an increasing role and fee for service diminishes as episodic payments prevail—going to have to find a way to support their oncologists in an environment where reimbursements will shrink.

I am also wondering how the academic oncology centers are going to survive, unless they get a genuine hold on their costs of care, become more efficient and effective in care delivery, and find ACOs that are willing to work with them. The alternative is that they may find themselves in a decade or so high and dry with no one willing to send them anyone except the more complicated patients. That would be a huge loss for cancer care in the United States.

The development of this new "system" in the Carolinas will be fascinating to watch, and in fact I suspect there are many of us who wish we had a role in helping define such a challenging opportunity. Hopefully they will be successful, but the odds are not in their favor given the inertia in our health care delivery system, the breadth of their territory and the diversity of the communities they serve.

In closing, being a community oncologist in the mid-1970s was not exactly a simple path to riches. We put a lot on the line to get things started, without much reward, claims made to the contrary. Clearly oncology practice has advanced considerably over these past decades, yet challenges abound. The Carolinas' commitment to addressing the many issues that confront us in cancer care—as well as other similar efforts throughout the country—will hopefully show us the way to a more cohesive and successful model to deliver effective and comprehensive cancer care than we have seen to date.

— Len Lichtenfeld, deputy chief medical officer, the American Cancer Society

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