THE CANCER LETTER

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

Vol. 37 No. 30
July 29, 2011

SPECIAL ISSUE

A Year at NCI: Part 2 of a Q&A With Varmus As He Reflects On Prevention, Detection, Drug Development and Healthcare Reform

NCI Director Harold Varmus sat down for a conversation with The Cancer Letter. This portion of the interview focuses on the following subjects:

• The significance of the National Lung Screening Trial. Can there be another trial like it in the future?

• Looking at detection trials differently, perhaps phase I, II and III detection trials.

• Re-examining the configuration of NCI: How money is distributed among divisions.

• Reassessment of SAIC-Frederick.

• Redesign of the NCI clinical trials cooperative groups. The most interesting phase is yet to come, Varmus says.

• What the NIH National Center for Advancing Translational Sciences can accomplish.

• The role NCI can—and cannot—play in health care reform.

• Why the job of the NCI director is a challenge to fill.

The interview was conducted by Paul Goldberg, editor and publisher of The Cancer Letter on July 18.

Paul Goldberg: ***Let's move on to the National Lung Screening Trial. That had to be a highlight of the year for you.***

Harold Varmus: Yes. NLST was, first of all, an educational experience for me. I was excited to have a definitive result, and a result that really matters to public health. Having a screening method that actually works is very exciting.

(Continued to page 2)

In Brief:

Kramer to Head Division of Cancer Prevention As Institute Explores "Molecular Thinking"

BARNETT KRAMER will be the next director of the NCI Division of Cancer Prevention, Institute Director Harold Varmus announced at a "town hall" meeting July 27.

"Not all the paperwork has been signed as yet, but I'm taking the risk of saying that it will be signed," Varmus said at the gathering that marked his first anniversary of taking the job at the institute.

"I'd like to see more molecular thinking in the world of cancer prevention," Varmus said. "Barry and I discussed and agreed this needs to be the case.

(Continued to page 9)

Making the Most of $5 Billion: Varmus Rethinks The Institute

(Continued from page 1)

PG: Given the financial state of the institute today, is it possible to imagine another such trial being done? Is the era of large randomized prevention and screening trials over?

HV: I think the answer is choosing your prevention trials or screening trials wisely.

Could there be ways to do trials on a smaller scale and lead up to a bigger scale?

One way to think about NLST from the funder's perspective is, "Are there questions that emerged from NLST that we need to pursue?"

As you know, we are trying to find new leadership for the Division of Cancer Prevention, the division that has been largely responsible for screening [Varmus earlier this week said Barnett Kramer would take the top job at DCP. See story, p. 1].

One way to think about NLST from the funder's perspective is, "Are there questions that emerged from NLST that we need to pursue?"

And I would say the answer is fully "Yes."

One of them is: "Can we make good use of the specimens that were collected during NLST to begin to understand more about how lung cancers arise? And whether these samples could be useful in devising biomarkers. Because, you know, NLST-based screening is definitely an imperfect process.

One of the things that worries me, frankly, is how this will do as it gets extended into a much broader community.

That will be influenced dramatically by what the U.S. Preventive Services Task Force says and what CMS [the Centers for Medicare and Medicaid Services] says about what will be funded. And by what FDA says about its responsibility for monitoring the devices, because there is a potential large variability in radiation that's delivered by these screening devices.

In any case, in addition to what can be learned by mining the samples that have been collected, there are the unanswered questions: "What happens when you extend the age-group? When you change the frequency of screening? When you change the follow-up?"

A very large fraction of these older heavy smokers who undergo CT scanning have a positive finding, as much a quarter or even half in different studies.

You have to make a very reasoned decision about how to follow these up. Can they develop better guidelines? Maybe.

Would we have greater success in reducing mortality by doing screening more frequently? That's possible.

Like the data would suggest, we failed to detect a lot of the cancers that proved to be lethal because the reduction on cancer-specific mortality was only 20 percent. Twenty percent is definitely very significant, but it's 20 percent, not 80 percent, and that could be interpreted as meaning that many of the lethal cancers were on the rise quite quickly and were not detected by the screening procedure, which was, in this case, done annually for three years.

Maybe if we had done screening every six months, we would have found more things that were potentially lethal. I don't know. It's very hard to say.

PG: What about the trial itself? Do you see more smaller prevention trials? Do you seen another PLCO, another NLST coming up any time soon?

HV: I don't see it soon, but I think there might be questions that arise from NLST that we would pursue on a smaller scale.

I hope to discuss with my new Prevention Division director how we might be able to do something that is analogous to phase I, II, and III trials in the therapeutic domain.

We should think through how we go about initiating the trials. What are the biological bases for

THE CANCER LETTER

® The Cancer Letter is a registered trademark.

Editor & Publisher: Paul Goldberg
Copy Editor: Conor Hale
Intern: Ridge Montes

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

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

thinking the screening might work or might not work? Are there ways to develop confidence that it might or might not work? So, these are things worth cogitating because, as you point out, the expense of these studies is great. Now, I would also like to put the price of NLST in context.

It does sound dramatic when you say 53,000 patients, $240 million—but of course, that was not spent in one year. That was spent over about eight years. When you put the cost of NLST in the context of a couple other things: one is the total budget of the NCI, and the more important issue is the cost of either not screening and having people die of lung cancer after having been treated for it, or the cost that eventually will be borne by Medicare and other payers when the screening procedure is developed.

We are not deeply impoverished... We still have about $5 billion a year to spend, and we do have to choose our greatest scientific opportunities and public health demands, and fund those studies.

These are big costs, and they completely dwarf the cost of NLST, $240 million over the whole study.

Others have estimated that if people simply used the helical CT screening more or less the way it's outlined in that study with that patient population, the cost would be somewhere in the range of $2 billion to $4 billion a year.

PG: So you are really talking about something smaller and smarter.

HV: Possibly.

PG: Let's look at the history of NLST. It starts with The Lancet paper [in July 1999, by Henschke, et al.], and there was a story in The New York Times, and lots of excitement in the community. Instead of settling for inconclusive data, [former NCI Director] Rick [Klausner] said NCI must look into how screening is affecting cause-specific mortality.

Do you see yourself seeing something in The New York Times and saying...

HV: Not the New York Times, but I think if there is a good idea for screening, and if I think it would make a big difference if we do the study, the study will get done.

We are not deeply impoverished.

The NCI is dealing with reductions that are always difficult to adapt to, but I keep emphasizing to everybody that we still have about $5 billion a year to spend, and we do have to choose our greatest scientific opportunities and public health demands, and fund those studies.

PG: I used to argue in recent past that NCI should have been put in receivership. Some of these programs are still there, and you can put them away and apply recovered funds to something useful.

HV: I'm not sure it's fair to say—programs all turn over at some level. They get reviewed, and grants come to an end, so some things tend to have a longer staying power than others, but the turnover is reasonable.

What I think is interesting is how the whole institute is configured, and how money is allocated among the divisions and among the centers, and how much goes towards tobacco, or for clinical trials, or for intramural research.

It's definitely hard to move funds among those areas. There's no doubt that we need work in all those areas, but are they appropriately budgeted?

We are having a retreat this week, and one of the things we are doing is a budget exercise based on zero budgeting. How would you build your division if you had 75 percent of what you have now? Or 125 percent of what you have now?

That's an interesting exercise.

It's interesting...how money is allocated among the divisions, ...how much goes towards tobacco, or for clinical trials, or for intramural research. There's no doubt that we need work in all those areas, but are they appropriately budgeted?

PG: What is your vision for SAIC-Frederick?

HV: Well, a couple of things. But we are off on a different topic now.

PG: Well, it's the same topic.

HV: Yes and no. It is in the sense of talking about oversight. I think that having a major contract, a federally-funded research and development contract, is a very important thing for the NCI—and for the NIH.

Frederick serves a lot of NIH institutes, not just ours, but we hold the contract and we are the biggest player up there. A couple of things have happened. One is that we've gotten a great new person to be the CEO of SAIC-Frederick, David Heimbrook.

That'll be a big help.

PG: You played a role in selecting him...

HV: I didn't choose him on my own. There was a search committee. SAIC, obviously, has to make the decision, but I was involved, and some of my colleagues were involved, and that was very, very helpful.

We've already all been out to dinner together, and Dave wants to be part of the NCI. He's not, obviously, employed by the NCI, but he wants to be working closely with the NCI.

This is the only large contract program in [HHS]. It's a real privilege to have it, and I want to make sure that it's used optimally... I know from being up there that we have some sterling scientists doing some very interesting things.

I want to think of this as NCI's contract program, just the way that DOE has its contract sites. One of the ways in which I'm going to make the whole Frederick campus into one whole is by appointing an advisory committee, chaired by Zach Hall and populated by terrific scientists, to give me guidance. By referring to the whole Frederick enterprise I mean the elements that are bona fide NCI, paid by the NCI—like parts of the Center for Cancer Research, and our SAIC contract program, and the new Riverside Park that will have biotech start-ups.

The new advisory committee will be reporting to me, not to SAIC, on how the campus is developing, to be sure we are doing all the things we can do with a program that is largely under contract and a program that is, unfortunately, about 30 miles away from Bethesda.

That's a geographical constraint that some people think has advantages. I would rather see it closer.

PG: A long bike ride.

HV: I think that giving an outstanding bunch of outside advisors a chance to look not just at the individual components, but the whole enterprise will be a good thing for us.

It seems to be a rallying cry—folks want to have clinical trials that are more clearly based on these scientific findings...trials that are genetically informed give us useful information, whether they succeed or not.

I can't be up there much of the time, but I feel that having more engagement—in part through this advisory group—will allow us to feel that we are taking advantage in an optimal way of the flexibility that we've been given.

This is the only large contract program in the Department of Health and Human Services. It's a real privilege to have it, and I want to make sure that it's used optimally. For most people, on the outside, it's pretty opaque. And yet I know from being up there that we have some sterling scientists doing some very interesting things.

We have a view of the individual components, but what we need to do is have a broader view of what we are actually using it for.

PG: What is the next phase? The first phase is about looking at some of the things that have been done which shouldn't have been done and looking at the clinical trials cooperative groups.

HV: These things are not over.

Reorganizing the cooperative groups—there has been a lot of progress there, but there is quite a ways to go to make this work perfectly.

Actually, I think the initial phase was not the interesting part. I know it is interesting to people who have been politically involved in these cooperative groups over the years. There was a problem of condensation, integration, and reorganization that was of great interest to people in the groups.

But to me, the interesting part is now acting on the claim that everybody has made—and it seems to be a rallying cry—that folks want to have clinical trials that are more clearly based on these scientific findings; trials in which clinical center directors feel they have some role, in addition to the obvious roles played by the leaders of the cooperative groups; trials that are genetically informed give us useful information, whether they succeed or not. That's the part of it that I find very interesting.

PG: Do you care whether there will be three tissue banks? Or four? Or some other number?

HV: No. A reasonable number. I want to see the tissues used well and I want to see a wise and careful collection that allows the kind of analysis The Cancer Genome Atlas has become expert at done efficiently.

PG: So you don't see any change of focus. You are going to continue the work you started?

HV: I think there is a change of focus. The trials that we hope to see done will be—I hope—more closely scrutinized by the disease oversight groups, with a real eye to solving the scientific problems in modern cancer therapy.

I think we can use the clinical trial cooperative groups in a much more productive way: bringing scientists with a genomic orientation, for example, together with the trialists; making sure that we are getting the right samples; doing the right things, even figuring out things like whether we can predict who is going to respond to one therapy or another.

There is no doubt that, as the healthcare bill becomes part of the way in which American medicine works, the information that the NCI or NIH provides to the public and to health care providers and to patients will be part of the landscape.

Which brings us back to the issue raised earlier: How do we make use of information?

PG: Can NIH and NCI play a role in health care reform? How can this be done in the context of the NCI portfolio? Do you look for more and more targeted drugs?

HV: The NCI has got to operate with a scientific orientation.

We are trying to understand cancer, develop evidence that is used now to make decisions by the FDA, by the CDC, and anyone else who is doing health policy, whether it's prevention or treatment.

We are not going to be running health care. It's never been our business. But we do research that fits the bill of comparative effectiveness, a landscape that's continually changing, but there is no doubt that, just as we've compared X-ray with helical CT scanning, or as we compare one drug with another, we are comparing the effectiveness of different treatments. There is no doubt that, as the healthcare bill becomes part of the way in which American medicine works, the information that the NCI or NIH provides to the public and to health care providers and to patients will be part of the landscape.

PG: I guess you talk about NCATS [the NIH National Center for Advancing Translational Sciences] a fair amount, even though it's really not about NCI.

HV: I don't talk about it that much.

PG: You talk about it some. It's clearly an important way of looking at this question of drug development perhaps in a smarter way.

HV: NCATS will succeed if it actually does two things.

One is provide some core facilities that we can all use to take advantage of a rapidly changing technological infrastructure, and, secondly, if it develops some process elements that work well in the context of the kind of research we support, interfacing in a productive way with industry.

Because the trade-off to industry here is going to have to be very smooth, and knowing how far NIH-supported research should take projects that are directed toward making devices, drugs, biologicals, and diagnostic kits, and so forth, is pretty critical.

Having a testing ground within NCATS will be potentially very important.

PG: It's very difficult for me, as someone who covers this stuff, to understand these issues based on the FDA perspective. It's a little easier from the NCI perspective, because it has to be a scientific issue more than it is a regulatory issue.

HV: Most of what we are doing is pre-FDA.

I sometimes have a hard time trying to categorize research into these compartments that people call "basic," "translational," and "clinical," because there is a continuum without sharp boundaries, and people move back and forth, and a lot of things people think are translational—to my way of thinking—are really basic research.

I sometimes have a hard time trying to categorize research into these compartments that people call "basic," "translational," and "clinical," ...a lot of things people think are translational—to my way of thinking—are really basic research.

My own lab's experience, for example: we've been doing some high throughput drug screening, but my primary goal has not been to develop a drug. We are trying to use drugs as tools to find potential targets. By "targets," I mean vulnerabilities in cancer cells that reflect the ways in which a normal cell becomes a cancer cell or remains a cancer cell.

We are looking for research tools, but I think that

there is always the potential of a spinoff. I don't know whether to call the research I do these days "basic" or "translational." It's certainly disease-specific, and it has some properties that are characteristic of what others are calling translational research.

I'm a little worried when I hear the term "translational" overused by people who defend grant applications, for example, by saying, "It has translational potential."

For me, what matters is whether a grant application has the potential to make a discovery that changes our way of thinking about how a normal cell becomes a cancer cell or how a cancer cell behaves.

And, yes, everything that we do that enlarges our understanding of cancer as a disease ought at some level to have some potential impact on the way we promote the nation's health by making use of biological knowledge.

It's a tricky terrain, but I am concerned that we not become so obsessed with meeting the litmus test of "translatability" that we lose sight of the fact that it is fundamental discovery that NIH does best and ought to be the bedrock of what we do.

PG: So it's more of a story-telling and provocative questions?

HV: Well, yes and no. I don't want to overdo that, because there are many things that we are learning, for example through TCGA [The Cancer Genome Atlas], that are not really the result of asking a "provocative question" TCGA is asking a really obvious question: Now that we have these great genomic tools, how do we get a complete picture of the landscape of the cancer cell?

We now can count the copies of all genes, we can look for mutations by whole genome or whole-exome sequencing—we can look at the constellation of important proteins in a pretty sophisticated way.

Getting all this stuff catalogued and probed will be critical in thinking about how a cancer cell differs from its normal counterpart—these are pretty straightforward things to do, and they don't rise to the level of provocation.

Now, some the things we are learning do become provocative issues. Some people have been troubled that the ovarian cancer project, which was recently published, has not given us a list of 15 juicy oncogenes that are each mutated in 15 percent of ovarian cancers.

Instead, the original mutations seem to be quite rare, and the dominant theme is—aside from P53 mutations, which are practically universal—the dominant theme is DNA rearrangement.

Well, to me, that is a very provocative finding that says, "Can we understand the nature of these rearrangements well enough to understand what rearrangements are selected for during the growth of an actual cancer clone?" But it also raises the very intriguing question of whether we can use the apparent instability of the genome as a target in therapeutics.

PG: So you don't really spend a lot of time worrying about FDA drug approval criteria?

HV: We are interested in it, but that really is the FDA's job. Of course, we are interested in it, because the design of our clinical trials will be influenced by it.

PG: But you personally don't think about it a whole lot?

HV: I rely heavily on Jim Doroshow [NCI deputy director for clinical and translational research] to work with Rick Pazdur [director of the FDA Office of Oncology Drug Products], and it's not something that I spend a tremendous amount of time thinking about. But I am concerned with some new twists and turns here that we discussed earlier.

It's very clear that multi-drug therapy has always been part-and-parcel of cancer research, and will need to be part of the design of clinical trials, even when we have multiple drugs that are not yet approved.

I am concerned about what the conditions will be for use of certain drugs, what sort of criteria will be recommended or required by the FDA for certain drugs to be used. That's going to affect the way that insurers and state and federal care programs, Medicare and Medicaid, reimburse.

The other issue that I think is going to be very, very interesting—we are having discussions with the FDA about this—is how we do drug approvals in the context of multi-drug therapy.

It's very clear that multi-drug therapy has always been part-and-parcel of cancer research, and will need to be part of the design of clinical trials, even when we have multiple drugs that are not yet approved.

PG: I guess—and this is my last question—correct me if I'm wrong. You were on the search committee that was looking for the NCI director…

HV: That's not strictly true. That was not a search committee. That was group of people who were acting in an advisory capacity to try to find candidates.

PG: And the job was offered to a bunch of

people...

HV: No. That is absolutely wrong. The job was offered to nobody.

PG: Really?

HV: Many people were interviewed by members of the committee.

PG: So the job was not offered to* anybody*?

HV: Not to my knowledge.

PG: I see what you are saying, only the President of the United States could offer the job—so in that sense, yes, absolutely.

HV: Several people were interviewed.

PG: And several people declined to go further?

HV: They didn't want to go further. That's very different from turning down a job.

PG: Got it. I stand corrected. I guess I'm wondering why they didn't want to go further. This should be a fantastic job. You scoped it out from over there [NIH Building One, the Office of the Director.]

HV: But let's face it. This is a job that offers less financial compensation than many people can obtain in other ways.

Some people value very highly their connections with industry, which can be a lot of fun as well as being economically satisfying and emotionally satisfying. And we have government rules that make my life a living hell sometimes.

There are some things that I've been compelled to do that I think are patently ridiculous: like leaving the Lasker Prize jury, or not being a board member at Public Library of Science. I find this stuff absurd. And working within travel restrictions is very laborious. People who reach a senior stage in life and who've been used to a much easier way of living don't want to take it on.

It's not all easy, but it is—for me personally—very rewarding to be here, and I don't have a moment's regret about having taken this on.

PG: I see you are clearly having a very good time. I've seen some NCI directors having a terrible time with this job. How do you actually make this a job that people would really want?

HV: Pay four times as much and lighten up on some of the restrictions.

PG: Yeah, but do you really care?

HV: Do I care? No. I personally don't care. But you asked why other folks...

PG: It's about money?

HV: It's part of it. People have traditionally wanted to have strong scientists in these positions, and there is no doubt that my own ability to run a laboratory has been imperilled by the demands of the job.

I still have a small lab, which I try to run with a reasonable degree of responsibility, but I'm not giving as much attention to my post-docs as I'd like to.

There are people who are in the middle of their research careers who say, "There are some things that I really want to accomplish scientifically and I don't think I'm going to accomplish them by taking on that administrative role."

The salary and the freedoms of motion are important, but one key element in getting leading scientists in this country to take this job is that you just can't do everything.

If you want to take your science seriously and also run the institute in a serious way, something's got to give. If I had been approached for this job when I was 42 years old, I would have said "No. I'm enjoying doing my science and my teaching, and I'm not ready for that." It can be a one-way street: that is, get outside the active running of a large lab for more than a few years and it's hard to get back into it.

The salary and the freedoms of motion are important, but one key element in getting leading scientists in this country to take this job is that you just can't do everything.

If you want to take your science seriously and also run the institute in a serious way, something's got to give. If I had been approached for this job when I was 42 years old, I would have said "No. I'm enjoying doing my science and my teaching, and I'm not ready for that."

PG: Thank you very much.

HV: Sure.

Follow us on Twitter: @TheCancerLetter

Last week:

• The intellectual underpinnings of the "provocative questions" initiative, Varmus's signature program.

• Reflections on the pleasure of a biking commute.

• The fortuitous aspect of the Duke Scandal: it focused attention on the challenge of bringing genomic technologies into oncology practice.

• The difficulties—and opportunities—the NCI's current financial difficulties present.

• The demise of the "payline." The new process of deciding on funding grants that fall into what Varmus calls "a zone of uncertainty."

Last week's issue is posted at:
http://www.cancerletter.com/articles/20110722

Debt Ceiling Negotiations:
Groups Urge Congress, White House Not to Cut Medicare Reimbursement

By Ridge Montes

Cancer groups are urging Congress and the White House to refrain from making a $3 billion cut in the Medicare reimbursement for cancer drugs.

Last week, 19 healthcare organizations and patient advocacy groups said the funding cut would reduce Medicare reimbursement for Part B drugs (including antineoplastic drugs and biologics) to the Average Sales Price plus four percent.

"[This is] an unsustainable reduction that already financially strained community cancer centers cannot endure without cutting vital care services or closing altogether," the letter states.

Medicare reimbursement was reduced to ASP plus six percent in 2004, causing many practices to close or consolidate.

According to a survey conducted by the Community Oncology Alliance in March, "over the past three years, 199 cancer clinics have closed and 369 practices, with multiple clinic locations, are struggling financially," the letter states.

"The problem is only exacerbated by the fact that nearly two-thirds of all cancer diagnoses in the U. S. are in people over the age of 65, the primary recipients of Medicare coverage," the American Society of Clinical Oncology said a statement. "These patients are often already living on a fixed income, and being forced to travel outside their local communities will hinder their access to care and drive their costs up."

Instead of the proposed funding cut, the letter cites two bills—H.R.905 and S.733—as an alternative more likely "to improve the viability of community cancer care."

The letter, dated July 18, was sent President Barack Obama, Speaker John Boehner (R-Ohio), Senate Majority Leader Harry Reid (D-Nev.), House Majority Leader Eric Cantor (R-Va.), Senate Minority Leader Mitch McConnell (R-Ky.), and House Minority Leader Nancy Pelosi (D-Calif.).

The text of the letter follows:

To help protect the interests of individuals with cancer, the undersigned organizations, representing patients, distributors, and over 30,000 health providers who treat millions of Americans with cancer, urge you to oppose the $3 billion in cuts to Medicare reimbursement for cancer-fighting drugs and biologics that Members of Congress have discussed in the context of the national debt ceiling. Enacting a significant reduction in Medicare drug reimbursement would be devastating to both community cancer clinics and their patients. Due to the financial and administrative burdens that currently exist, community oncology practices already are reducing services and closing their doors across the United States at alarming rates. Additional Medicare cuts will result in a delay of services if providers are forced to eliminate or cut back on services. According to one study, over the past 3 years 199 cancer clinics have closed and 369 practices, with multiple clinic locations, are struggling financially.

Specifically, practices already face significant Medicare cuts imposed on chemotherapy drugs and services. The cumulative effect of these cuts is compounded by the fact that chemotherapy agents are reimbursed at artificially low rates under Medicare because manufacturer-todistributor prompt pay discounts are included in the calculation of average sales price. In recognition of the dire financial reality currently facing community oncology practices and the access impact to Medicare beneficiaries fighting cancer, almost 50 bipartisan Congressional leaders have co-sponsored HR 905 (Whitfield/Green) and S 733 (Stabenow/Roberts) to improve the viability of community cancer care. The cuts currently under consideration take the exact opposite direction from the changes these leaders recognize must be made to preserve the nation's cancer care delivery system.

As community-based cancer practices are forced to limit services and close, Medicare beneficiaries and other patients with cancer will face barriers to access to care. Forcing cancer patients to travel outside of their communities for oncology services often results in duplicative and unnecessary services, additional co-pays, and physical and emotional suffering. In addition,

closures result in job losses in the affected communities for skilled professionals such as oncology nurses, physician assistants and administrative staff.

In the face of the Medicare changes enacted through health care reform, we urge Congress to refrain from targeting for dramatic cuts the vulnerable Medicare population that requires life-sustaining cancer therapies. Congress can protect the interests of both the Medicare program and Medicare beneficiaries by promoting evidence based medicine, not through wholesale cuts. We share your goal of ensuring that cancer patients have access to affo rdable, quality, cancer care. At this time of great promise in cancer treatment, and as we face increasing incidence of cancer and a projected workforce shortage in oncology, we urgently need to strengthen the nation's cancer care delivery system, not weaken it. On behalf of the millions of cancer patients, we ask you to remove these debilitating cuts to cancer drugs and biologicals under Part B.

Thank you for your consideration of this urgent request.

Signed,

American Association of Clinical Urologists
American Society of Clinical Oncology
American Urological Association
AmerisourceBergen
Association of Community Cancer Centers
Association of Physician Assistants in Oncology
BDI Pharma
Cardinal Health
Community Oncology Alliance
Health Coalition, Inc.
Healthcare Distribution Management Association
Large Urology Group Practice Association
Leukemia and Lymphoma Society
McKesson Corp.
National Coalition for Cancer Survivorship
National Patient Advocate Foundation
Society of Gynecologic Oncologists
The US Oncology Network
UPMC Cancer Center

Obama: Medical Research One of Nation's Fiscal Priorities

By Ridge Montes

In the midst of the debate over raising the debt ceiling, President Barack Obama listed medical research among the top priorities of the federal government.

"The debate right now isn't about whether we need to make tough choices," Obama said in a televised speech July 25. "We all want a government that lives within its means, but there are still things we need to pay for as a country—things like new roads and bridges; weather satellites and food inspection; services to veterans and medical research."

In a letter to the White House, Joseph LaManna, president of the Federation of American Societies for Experimental Biology, thanked President Obama for naming medical research as one of the country's priorities.

"We were thrilled to hear you mention medical research during your address to the nation last night on the debt ceiling negotiations and agree that research is one of the things we need to pay for as a country," LaManna said in the letter dated July 26. "Thank you for once again unequivocally stating that investing in research must be a national priority."

In Brief:

Kramer to Head NCI Division; U-M Launches Patient Website

(Continued from page 1)

"Think about the effect of finding in cancers the molecular residues of carcinogenic viruses, like human papilloma viruses or hepatitis B viruses have led to vaccination programs that have been among the most important tools in cancer prevention we've developed over the last few decades," Varmus said. "Then there is a more general set of concerns having to do with understanding relationships between genes, environment, and behavior."

Kramer recently retired from his job as NIH associate director for disease prevention and director of the NIH Office of Disease Prevention. Kramer divided his time between the NCI Physician Data Query and JNCI, where he retained his position as the editor-in-chief. He also continued to serve as editor-in-chief of the PDQ Screening and Prevention Editorial Board (The Cancer Letter, Jan. 7).

JNCI is published by Oxford University Press and is not affiliated with the NCI.

When he was an NIH employee, Kramer's editing of JNCI was an approved outside activity. Now that he is re-entering federal service as an employee, approval by the NCI ethics office will be required for the remainder of his term as editor of JNCI. His current term and contract as editor ends next July.

Kramer said he intends to keep his position at PDQ.

ABHIJIT PATEL, of Yale University, and **DAVID KOZONO,** of Dana-Farber Cancer Institute, each recieved the 2011 American Society for Radiation Oncology's Junior Faculty Career Research Training Award.

The two-year award, of $100,000 per year, is presented annually to a board-eligible physician, physicist in radiation oncology, or radiobiologist who is within their first three years of their junior faculty appointment.

The society also announced the winners of its Residents/Fellows in Radiation Oncology Research Seed Grant Awards, one-year grants of $25,000 each.

The grants are presented to residents or fellows planning a career in basic science or clinical research.

The recipients are **MICHAEL PACOLD** of Dana-Farber Cancer Institute, **YOUNG CHA** of Vanderbilt University, and **DAVID LEE** of William Beaumont Hospital Research Institute.

Winners were selected by ASTRO's Research Evaluation Committee.

MARK LEMA was named recipient of the American Society of Anesthesiologists **Distinguished Service Award.**

Lema is chair of the Department of Anesthesiology and medical director of Surgical Services at Roswell Park Cancer Institute.

He is also professor and chair of anesthesiology at the University at Buffalo School of Medicine and Biomedical Sciences, as well as associate research professor of experimental pathology in UB's Roswell Park Graduate Division.

Lema, who is also currently president of the Medical Society of Erie County, served as the 71st president of ASA in 2007 and treasurer of the World Federation of Societies of Anesthesiologists in 2010.

"It is the pinnacle of any physician's career to be recognized for meritorious service by an organization as well-respected as the ASA," Lema said. "To be selected for this honor among 46,000 peers is deeply humbling, and I'm extremely grateful for this recognition."

Lema will receive the award at the ASA's annual meeting October 17.

THE UNIVERSITY OF MICHIGAN Comprehensive Cancer Center launched **MCancerTalk.org**, a new website that offers articles, advice from university healthcare professionals, and open forums for patients, survivors, and caregivers to discuss and ask questions.

The forums are moderated by university cancer center staff. Physicians and registered oncology nurses from the U-M Cancer AnswerLine respond to questions posted by members.

"There is so much value in cancer survivors and caregivers sharing their experiences and having a secure place where they can talk with others who know what they are going through," said Becky Eggleston, manager of the AnswerLine. "People want to know they're not alone."

FDA News:

FDA Approves REMS For Pain Control Medications

FDA approved a Risk Evaluation and Mitigation Strategy for Fentora (fentanyl buccal tablet) and Actiq (oral transmucosal fentanyl citrate). Both products are indicated for the management of breakthrough pain in opioid-tolerant patients with cancer.

The newly-approved REMS will replace the existing risk management programs for Actiq and Fentora.

To prescribe these drugs, pharmacies and healthcare professionals must enroll by completing an education module and a knowledge assessment focused on safety information and appropriate patient selection.

"The program provides education and systems to support safe use of Fentora and Actiq, preserving availability of the medicines to patients through retail pharmacies and using other systems already familiar to prescribers and pharmacists," said Lesley Russell, chief medical officer at Cephalon Inc.

Enrollment in the REMS program will begin in September 2011. After a six-month transition period following the launch, no prescription may be dispensed unless the prescriber and pharmacy are enrolled.

Cephalon will provide FDA with regular updates on the effectiveness of the REMS.