THE CANCER LETTER

May 15, 2015

www.cancerletter.com

Vol. 41 No. 19



Conversation with The Cancer Letter

Fisher Discusses Turnaround at Fox Chase

A year ago, Fox Chase Cancer Center was losing money—\$17 million in 2014

In 2015, the losses have been stopped and an \$8 million operating profit is projected.

Fox Chase is part of the Temple University Health System, which is rebuilding its cancer services around the venerable center.

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21st Century Cures Passes House Subcommittee

By Matthew Bin Han Ong

The 21st Century Cures bill—a bipartisan initiative aimed at streamlining development of drugs and medical devices—received unanimous approval May 14 from the Health Subcommittee of the House Energy and Commerce Committee.

Congressional leaders expect a full committee markup next week, and a floor vote in June.

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Guest Editorial

AACR: 21st Century Cures a "Model for An Open and Honest Conversation"

By José Baselga and William S. Dalton

Almost one year ago (on April 30, 2014), House Energy and Commerce Committee Chairman Fred Upton (R-Mich.), along with Oversight and Investigations Subcommittee Ranking Member Diana DeGette (D-Colo.) announced the launch of 21st Century Cures, an initiative aimed at accelerating the pace of cures and medical breakthroughs in the United States by ensuring that our laws are keeping pace with innovation.

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After Two Years of Losses, Fox Chase \$8 Million in the Black

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"We're in an interesting time at Fox Chase—because as I look ahead to the future of health care and accountable care coming, I think it's unlikely if many, if any, of the freestanding cancer centers will be able to stand by themselves in that kind of arrangement," Fisher said to The Cancer Letter. "So right now, we're a fascinating model that's going to be looked at by our colleagues to see how it works."

Here are the changes that occurred over the nearly two years since Richard Fisher was named director, president and CEO at Fox Chase:

- New patient appointments went up by 14 percent and online registrations by 41 percent after Fox Chase started to offer new patients next-business-day appointments.
- The number of surgical patients went up by 15 percent over last fiscal year, and is on pace to exceed 5,000 cases in the operating room in FY15.
- The number of grants awarded by NIH to Fox Chase went up by 50 percent over last year.
- An internal competitive grant process was launched, using the NIH peer-review to award grants for interdisciplinary translational cancer research projects, under the leadership of the new deputy cancer center director for translational research, Wafik El-Deiry.

How did this turnaround occur?

The Cancer Letter asked Fisher to talk about the turnaround, and describe his plans for Fox Chase in the competitive Philadelphia-area market. Fisher spoke with Paul Goldberg, editor and publisher of The Cancer Letter.

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PO Box 9905, Washington DC 20016 General Information: www.cancerletter.com

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Paul Goldberg: All cancer centers are different from each other. When you've seen one cancer center you've seen one cancer center. What is unique about Fox Chase?

Richard Fisher: I certainly agree with you in that regard. Fox Chase is a wonderful, fascinating place. As you know, it was one of the original four places, when I trained, where you could get cancer training. And it had a tremendous history as a freestanding cancer center, of which there are only about 11 in the country now.

It had tremendous research activity in the past—and what really still stands out today, whenever I talk to people, is that anyone who comes in for care comes into Fox Chase feels this culture of incredible patient care that is a cornerstone of the organization. And I get letters every day of the week from patients and families telling me how wonderful the doctors are, the nurses are, and the support they get. So there's a real culture of caring that goes throughout the organization.

There's been a very strong basic science presence over the years, resulting in all kinds of awards and things. And there's been a real control and prevention program, led largely by Paul Engstrom for many years, who is very well known in the field in that regard.

We're in an interesting time at Fox Chase—because as I look ahead to the future of health care and accountable care coming, I think it's unlikely if many, if any, of the freestanding cancer centers will be able to stand by themselves in that kind of arrangement. So right now we're a fascinating model that's going to be looked at by our colleagues to see how it works.

We're merged into a health system here, and I suppose we're the first in the group to do that. But it's an interesting experiment. It's working very well at the moment. And I think people are going to be looking forward to that in the future.

PG: What do you think went wrong before you came in at Fox Chase?

RF: The major problem that organizations all have is good periods and bad periods; they go through cycles.

The difficult cycle before me was largely precipitated by fiscal events. There was some construction of major facilities and buildings that was highly leveraged and protected by swaps. And, unfortunately, that happened right before the market went bad. Therefore, there was enormous strain on the fiscal resources of the organization.

That period ended when Temple University Health System came in and acquired Fox Chase. We became a wholly owned subsidiary of Temple Health, one of the family members of the corporations within Temple Health, and they retired that debt, refinanced it, and got us back to where we could start thinking about the future.

PG: Being a part of a large health system, and you're not alone in this, is it fair say that you are a freestanding cancer center?

RF: Well, it's a complicated story. We call ourselves a hybrid right now. We are still a corporate entity; I'm the president and CEO. We have our own CFO, we have our own board, we have our own finances, we have our own faculty, our own tenure system, etc.—but we are part of Temple Health, and within Temple Health, we now have the opportunity to move into their community and we're going to be the brand for all of Temple Health cancer.

So Fox Chase Cancer Center-Temple Health will be beyond the scope of just the original Fox Chase, but will be establishing, and has established, major parts of the cancer program in what we call the Broad Street campus, which is where Temple Medical Center itself is located.

PG: So the value of a cancer center to a large health system is the brand that was built over many years, as it was in this case?

RF: It's amazing in many regards. First of all, it gives the old Fox Chase access to underserved populations, because Temple University Hospital is certainly one of the major safety-net hospitals in the Philadelphia market.

That is something we didn't have, and the ability to affect the population is obviously going to be a big part of accountable care in the future. So we have that. And, in turn, we bring a new level of cancer research and care to what was Temple's health system.

So members of the faculty of the bone marrow transplant unit—for example, the medical oncology group—have now moved and become members of the Fox Chase faculty, while they are still giving their care in their respective locations. So we're moving throughout the system, integrating the surgeons, etc., and we will have common protocols and common quality controls, and really a much bigger cancer portfolio than Temple ever had.

And from Fox Chase's perspective, we'll be able to offer that to patients throughout the health system. We think it's a win-win for both organizations.

PG: When you accepted this job, did you have a prospective plan for turning the place around?

RF: I wish I could tell you that I knew everything ahead of time and had it all figured out, but it came relatively quickly, and we did some quick on-the-job learning.

We had a number of issues that we had to resolve. And I've been doing this for a while, so with the assistance of a great group of people here who were anxious to have strong leadership and move forward, we came up with a plan for what we were going to do. And that involves not only the fiscal health of the place, but also programmatic health.

PG: But as far as the numbers, what did they look like when you came in, and what do they look like now?

RF: Well the numbers are a very big change, an important change, and sometimes we wish we could not worry about the money, but of course we can't do that. It's critically important.

The first year I was here, the Fox Chase family—the Fox Chase corporation recorded a \$17 million loss, which is clearly unsustainable and not something we could live with. So we sat down with all of the programs and the administration, and we went line-by-line through the organization.

All of the clinical revenue from the organization at Fox Chase, all the margin, goes into supporting the research program. But it had become clear to me and to us as we went through the programs that, in many cases, we still had a probably an excessive amount of unfunded research being supported by the clinical revenue.

So we went line-by-line through that and looked at the programs, made very difficult decisions about what our core business was, what we could support, what was likely to be grant funded, etc., and we ended up taking \$20 million out of the budget in a six-month period.

Now, I don't believe that you can cut your way to prosperity, so we coupled that with an aggressive growth program. We were in the market, and marketing was reinstated. I started a program, which allows patients who call Fox Chase to be seen in the next business day. We call it our Rapid Access program. And it's really had an amazing result.

And this year, all of our clinical programs—the major ones that are fiscally important: surgery, radiation oncology, and infusion—are all up double digits; 10-15 percent. And this year, instead of losing \$17 million, we're probably going to end the year on an absolute positive note of \$8 million.

PG: That's a \$25 million split!

RF: It's a very significant turnaround for us. It enables us to do the things we need to do, make the investments we need to make, and continue to be a viable organization.

Obviously you can't lose those kinds of dollars very long before you cannot function. And we're very pleased that the organization is moving forward—and

although these are obviously difficult decisions to make, and difficult plans to institute, I think most people think we have a stronger, better organization now.

The morale of the organization is much better, and we're very optimistic and looking to a very bright future for Fox Chase as part of Temple Health.

PG: What were the programs that needed to grow and what were the money drains that needed to go away? Is there a way to summarize that?

RF: Some of this was simply if people hadn't had grants over a prolonged period of time—we can't continue to support them; we just don't have the resources in this day and age. Some of that was across the board.

But we did have some programs, which we probably weren't focused on appropriately. Our genomics program was heavily involved in technology. We were not competitive in that regard, so we shifted the emphasis of that program to looking at genomics in special populations and in unique biology, as opposed to technology. So that's kind of an example of a program that wasn't performing in a way that was viable over the long term.

What we needed to grow was really—as I said, the place has a great history—but we needed to increase our translational science. That's the new word of the day, and it's really where the advancements and progress is going to be made. So we wanted to make our investments in that.

We acquired, when we went into Temple Health, some very fine scientists down at Temple who added some very important programs to us. So suddenly we had an ability to do an epigenetics program. [Jean-Pierre] Issa down at the Fels Institute [for Cancer Research and Molecular Biology] is now a full member of Fox Chase's program and is now a program leader at our cancer center, and a very fine scientist.

We didn't have a critical mass for that. So we're looking at translational science; we're looking at epigenetics. And Fox Chase has never been a traditionally dominant player in hematological malignancy—as you probably know, when I'm not running a cancer center, that's what my world has been about for the last multiple decades—so we're making a big investment in coming to prominence in hematological malignancy.

PG: You have very strong competition. What would be the niche for Fox Chase in Philadelphia? I'm mostly thinking about the University of Pennsylvania and Thomas Jefferson. Where does Fox Chase fit in?

RF: This city is competitive. There are two comprehensive cancer centers, namely Penn and Fox Chase, and Jefferson is also a cancer center, but not a comprehensive one. We don't shy away from the

Fox Chase Cancer Center: FY 2013 to 2015

Year	Gross	Net
FY 2013 Actual	\$338,600,000	-\$3,046,000
FY 2014 Actual	\$334,500,000	-\$17,353,000
FY 2015 Projected	\$375,000,000	\$8,000,000

competition, my view is it makes us better—it keeps us sharper and performing well, so we welcome that.

There are also six million people in the metropolitan area of Philadelphia. There are a lot of people being seen in small community programs, which may or may not be the right thing, based on what they have. This market has not coalesced.

So what we think is, among other things, that we are a major player in what's called the two rivers strategy, which refers to the wedge that comes up in North Philadelphia between the two rivers, the Delaware and the Schuylkill, and goes up into the other parts of Pennsylvania. That's our location, and that's where Temple is, and no one is serving the underserved population in the north Broad Street/North Philadelphia area. So there's plenty of room, I think, for each of the three centers to be successful.

I think there's room for each to develop their strengths and their programs. And our niche is going to be in the areas where I feel we can be strongest, and in the populations that we are serving that are unique for that regard.

PG: Traditionally it was ovarian cancer, but what is it now? Is it still that or something else?

RF: Ovarian is still a big deal. We recruited Steve Rubin and Christina Chu from Penn, who joined us and now lead our gynecologic oncology program, which is largely ovarian cancer, of course. We recruited Henry Fung, who is the new head of our hematologic malignancy and transplant program. And that program is going gangbusters, and has increased its volume by about 30-40 percent already this year and is just doing very good things.

We're doing epigenetic therapy, not a surprise since we have a new program in that led by Dr. Issa and our clinical colleagues here. And in addition we have two very solid important teams, one in GU malignancy, led by Robert Uzzo, who's our chair of surgery, and is just world-class in that area. And the other in gastrointestinal disease, where one of our major new recruits is Wafik El-Deiry, who I can speak about in a moment, but is certainly coalescing our GI program and our colorectal program, and I think we're going to see some quite amazing things come out of that.

PG: This rapid appointment idea, is that novel? Is that done anywhere else? The guarantee that you will see a doctor right away...

RF: Every once in a while I have a good idea. And we jokingly call it I had a dream.

I walked into a town hall meeting with our faculty, and was thinking about it, and said, "Why do we have a lot of patients make an appointment and not show up after they've made that appointment?" We were having about 30 percent of patients in that regard. The cancer didn't go away, so they must be going somewhere else.

So we said wouldn't it be great—I know medically it might not make a difference—but how do you tell a cancer patient to sit tight for a week or so? It's really important that they see somebody. What if we offered them next-day service?

The faculty stepped up and embraced that. That's our Rapid Access program. Our number of no-shows on initial appointment is down to 3 percent instead of 30 percent. I think claiming it's the only one would be a mistake, because we haven't researched it, but there aren't many programs that offer that service.

And they're not seeing general oncologists. Over 90 percent of them are seeing subspecialty oncologists, who focus in the area of their particular disease. So we think it's a wonderful satisfier for our patients. It's increased our volume. And our doctors are working very hard to keep this happening.

PG: *It must be very difficult. The next day?*

RF: The next day. It's the next business day, to be perfectly accurate. We don't provide that service on the weekends at this time, but next business day is pretty good.

It's really an impressive thing, and our faculty has embraced it, and as I've said our clinical volumes are up 10-15 percent since doing that.

PG: I've never heard of this being done anywhere else.

RF: Well, I haven't either, but I don't want to claim that it's the only place. It's not done many places, and it requires a real dedication to this and we've been able to do it.

PG: When do you come up for your NCI grant review? Have you made any changes that would have an impact on the application?

RF: We're writing at the moment. This is the terrible last year for the cancer center director of the core grant, where we're totally immersed in that—we would be submitting in September of this year. So we're heavily engaged in it.

It will be a different application than they saw

before. Obviously, the leadership and the director have changed, the programs will have significant changes, and there will be new important people added.

So one works at this very hard; we think we have a good story to tell. We hope that the review committee and the NCI will be impressed by what we've done. We've worked very hard at it, and I think we're a much better organization than we've been previously.

PG: How's the recruitment going? I've heard you talk about it as the ASCO party last year. You said that Fox Chase is going to be a fun place to work.

RF: When you're losing money and people are leaving and people are discouraged and you can't do what you need to do to keep things going, it's not a good time.

And now, I think if you talked to our faculty, they're enthusiastic; the place is stabilized. They like the programs and the ways the leadership is functioning. There's just a whole new sense of optimism.

Like I've said, we've got some prominent and important people that have been added. And we're continuing to recruit as we grow and build. We're doing more targeted recruitment now for what we think will make a cohesive unit that can be competitive for certain kinds of grants. Wafik El-Deiry is probably my poster child at the moment. I hate to use that term, but you understand what I mean.

He's an outstanding investigator. He was at Penn and Penn State. He was a Howard Hughes investigator. He's an American Cancer Society full professor. He brought a million-dollar grant portfolio and about 16 people. He's our deputy director of translational science. He's hit the ground running and is meeting with all the disease-oriented groups, and he's really catalyzing a new view of that. He's turned out to be a great addition to our program, so we're very excited.

PG: Is there any other area that you're emphasizing that you haven't mentioned?

RF: There are things that we're thinking about and developing, but I think we've covered most of those.

PG: What are the long-range goals here? Where do you see Fox Chase five years from now? Ten years from now?

RF: I think these are very challenging times for health care. I don't have to tell you that; everyone knows that. I think these are very challenging times for cancer centers.

I think we are challenged, as the accountable care organizations come in, as populations get to be restricted in their movement—it's very important that we have a link to a health system in a baseline population. I think

we've accomplished much of that.

On the other side of the coin, in order to do some of the high-intensity research and other things we're on, we need probably resources that will not come in simply from the accountable care reimbursement. Therefore we're going to have to be a destination center.

I think there will be probably enough people with secondary or independent insurance that will continue to go to the places with the programs that they want to be treated in. So we hope to have a baseline of people in a fixed organization, and then be very competitive for new state-of-the-art research and programs that will bring people from around the region and even the country to get the kind of therapies that we hope to offer in the near future.

PG: Which areas do you think would make it even a national destination or even a worldwide destination?

RF: The programs were close to critical mass in the genitourinary malignancies—and I think you're going to see some amazing things shortly in GI cancer that are going to be very exciting coming out of these labs, and led, but not only led, by Dr. El-Deiry. Those are probably our two prominent programs.

I've built major national programs before, in lymphomas and with Dr. Issa and myself and Dr. Fung, I think we will have a major program in hematological malignancy. Those programs need to be competitive in a national basis. And we need to develop them in that regard.

House Subcommittee Approves 21st Century Cures Initiative

(Continued from page 1)

The discussion draft was introduced by full committee Chairman Fred Upton (R-Mich.), Rep. Diana DeGette (D-Colo.), Health Subcommittee Chairman Joe Pitts (R-Pa.), full committee Ranking Member Frank Pallone, Jr., (D-N.J.), and Health Subcommittee Ranking Member Gene Green (D-Texas).

The legislation is widely celebrated in the biomedical research community. If passed, NIH would receive \$10 billion over five years through a provision called the NIH Innovation Fund (The Cancer Letter, May 1).

"This bill does so much more," DeGette said in a statement. "It invests in advancing research to foster the future of science, it modernizes clinical trials, it encourages improvements in the drug and device approval process, it supports the development of new drugs and devices to address areas of unmet need, and it advances the important concept of precision medicine." On May 13, 180 organizations—academic research institutions, scientific and professional societies—signed a letter in support of the NIH Innovation Fund, which was included in the <u>updated discussion draft</u> published the same day.

The full text of the letter, spearheaded by Research! America, is available on their website.

Guest Editorial

AACR: 21st Century Cures a Model for "Honest Conversation"

(Continued from page 1)

Chairman Upton said at the time, "For the first time ever, we in Congress are going to take a comprehensive look at what steps we can take to accelerate the pace of cures in America. We are looking at the full arc of this process—from the discovery of clues in basic science, to streamlining the drug and device development process, to unleashing the power of digital medicine and social media at the treatment delivery phase."

During the past year, the Committee has held eight hearings, issued a number of white papers, and hosted more than two-dozen roundtables across the country to generate ideas for this initiative. The initial discussion draft, which was initially released in January, was the product of months of dialogue between members of Congress, patients, innovators, researchers, providers, consumers, and regulators. Yesterday, a House Energy and Commerce Subcommittee marked-up a revised 21st Century Cures Act and unanimously approved the measure. A full Committee markup of the bill is planned for next week.

During this open and inclusive process to develop the 21st Century Cures Act, the American Association for Cancer Research engaged with committee members and staff throughout the past year to ensure that the proposal advances basic, translational and clinical research, while recognizing the critical importance of maintaining both the National Institutes of Health and the Food and Drug Administration as national priorities.

In fact, the AACR is very pleased with many parts of the proposed legislation, including:

- 1) The Committee's commitment to increase funding for the NIH. Specifically, language is included that would authorize increased funding for the NIH through sustained, predictable increases of \$1.5 billion per year over the next three years, and an additional \$10 billion in mandatory funding over the next five years through the creation of a new "NIH Innovation Fund;"
- 2) The Committee's support for increasing participation of NIH scientists and FDA staff at

scientific meetings and conferences. Attending scientific meetings and research conferences is an important way for NIH scientists and FDA staff to stay connected with their respective communities and keep up with scientific advances;

- 3) The Committee's focus on streamlining data review at the FDA to modernize the drug development process without compromising patient safety;
- 4) The Committee's attention to expediting the approval of drugs designated as "breakthrough therapies." Many of these designations have already resulted in innovative, lifesaving therapies reaching cancer patients faster than they might have due to passage of the landmark 2012 Food and Drug Administration Safety and Innovation Act; and
- 5) The Committee's efforts to develop a sensible expanded access policy for investigational drugs.

Again, the AACR appreciates the Committee's willingness to revise and improve the bill based on the suggestions and ideas it receives from the medical research community, and we have provided some specific comments to this end, including:

- 1) Ensuring that the bill language and specific proposals are not duplicative or overly prescriptive. For example, the Committee directs NIH to identify mission priority areas even though the individual NIH Institutes and Centers are doing this during their respective efforts to develop their own strategic plans. In addition, the proposal for NIH to establish a Biomedical Research Working Group in Section 1023 appears unnecessary given that NIH already has three separate entities that oversee the grant proposal and submission process. The Scientific Management Review Board, the Center for Scientific Review and the Advisory Committee to the Director all consider ways to restructure, streamline and simplify the submission of grant proposals to the NIH. It would appear that these entities collectively have the authority and ability to do what is being asked of this new Working Group;
- 2) Ensuring that the FDA has the resources required to carry out the additional requirements that have been specified in the proposal. While seeking to support the NIH through additional funding, the AACR strongly believes that a parallel commitment is needed to ensure that the FDA has the resources it needs to carry out its regulatory and oversight functions, as well as to recruit, develop, and retain highly qualified staff. The need for additional FDA resources is quite clear, especially since the draft bill would require the FDA to issue more than 15 new guidances and hold several workshops and meetings within a relatively short time frame.

The AACR looks forward to continuing to work with the Committee as this process moves forward to address these and potentially other concerns.

In conclusion, the AACR and its 35,000 members applaud Chairman Upton and Rep. DeGette and their committee member colleagues and staff for how they have conducted their work during the past year. Since the beginning of this process, they have insisted on seeking ideas and input from patients and experts from all corners of the health care innovation infrastructure—from researchers and innovators at the drug discovery phase to manufacturers and scientists at the development phase to patients and health care providers at the delivery phase.

It's really been model for an open and honest conversation about how to do more and do better for patients, and for this we are very thankful.

Baselga is president of the American Association for Cancer Research, and physician-in-chief and chief medical officer at Memorial Sloan Kettering Cancer Center.

Dalton is chair of the AACR Science Policy & Government Affairs Committee, CEO of M2Gen, and director of the DeBartolo Family Personalized Medicine Institute at Moffitt Cancer Center.

ASCO Annual Meeting 2015 Highlights of Selected Studies

The American Society of Clinical Oncology announced results from four major studies May 13, which will be presented at the society's 51st Annual Meeting, May 29 to June 2, in Chicago.

The studies are:

- A large Australian trial showing that daily use of nicotinamide, a form of vitamin B3, for 12 months reduced the incidence of new non-melanoma skin cancers by 23 percent in patients at high risk for skin cancer.
- A randomized phase III trial finding that a new monoclonal antibody, elotuzumab, added to standard therapy, extended the duration of remission for patients with relapsed multiple myeloma by about five months.
- Findings from two phase III studies showing that children with Wilms tumor who have a specific chromosomal abnormality do better with a more intensive, augmented chemotherapy regimen.
- A large trial showing that men with newly diagnosed, advanced prostate cancer lived ten months longer, on average, when they received docetaxel chemotherapy along with standard hormone therapy.

These studies are among the 5,000 abstracts

publicly released in advance of the meeting.

Other major research, including studies selected for the meeting's Plenary Session, will be released as Late-Breaking Abstracts on-site at Chicago's McCormick Place and online on a rolling basis throughout the meeting. Around 25,000 oncology professionals are expected at the meeting, which focuses on the theme Illumination and Innovation.

"Trials like these are engines of progress for people with cancer of all ages," said ASCO President Peter Paul Yu. "In just four studies, we see the potential to spare thousands of people the stress and complications of a new cancer diagnosis, and to extend the lives of children and adults facing cancer in its most daunting forms. At ASCO's meeting in Chicago, we'll continue to see the transformative power of investments in cancer research and care."

Meaningful progress can still be achieved with conventional treatments, said Gregory Masters, chair of ASCO's Cancer Communications Committee.

"Thanks to a deeper understanding of cancer biology, we have a potential new targeted therapy for multiple myeloma, and can better tailor treatment for kids with Wilms tumor," Masters said. "At the same time, a simple vitamin pill and a long-available chemotherapy are being put to work in different ways to improve the lives of patients."

Study: Discrepancy in Definition Of "Value" in Cancer Care

The "value" of cancer care may be interpreted differently among health care stakeholders, according to a study by the Cancer Support Community, an international nonprofit.

The study, "Defining Value in Oncology: Perspectives from Patients with Metastatic Breast Cancer," asked 769 patients to define value, based on their cancer experience.

The study specifically looked at people with metastatic breast cancer who were members of the Cancer Experience Registry, an online initiative to capture and understand the experiences of those impacted by cancer.

CSC said the goal of the project was to better understand how patients define value so that the cancer community can identify strategies to bridge gaps between health care policy and practice to meet patient needs.

According to the Institute of Medicine, value is the "best care at lower cost."

Nearly 40 percent of respondents defined value in terms of a "personal value." For instance, one patient defined the term as, "Information and appropriate communication of that information at the right time and right place." Another patient defined it as, "Whatever is going to give me integrity."

On the other hand, 7.41 percent of patients defined value in terms of an "exchange value." For example, one patient said, "Value in cancer treatment is getting the best options at the lowest cost, presented to you in a manner that is easily comprehended."

Of the patients with a health-specific, exchange value response, 76 percent described treatment benefit as being engaged by or feeling close to their health care provider. Financial cost relative to benefit, or treatment efficacy was mentioned rarely.

In current discussions on the concept of value in cancer care, professional organizations and trade associations, such as the Institute of Medicine, the American Society of Clinical Oncology and others, are measuring value using an algorithm of clinical benefit, toxicity and cost.

This study underscores the importance of elevating the patient voice in these discussions, CSC said.

"Decisions are currently being made regarding how cancer care will be delivered and reimbursed in the future. These decisions must be based on real patient needs and expectations," said CSC President Linda House. "These study results reveal a disconnect in how patients define value and how it is being measured now by health care policymakers."

Additional findings revealed that value may not be as clear of a concept, with nearly 11 percent of the patients indicating they did not fully understand the question and 3 percent reporting "no value."

Forty-six percent did not answer the question, and no assumptions were applied to this group of respondents.

The full poster is available here.

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Report: Global Cancer Spending Reaches \$100 Billion Mark

Global spending on oncology drugs in 2014 reached \$100 billion, up 10.3 percent over 2013 and up from \$75 billion in 2010, according to the 2015 Global Oncology Trend Report, published by the IMS Institute for Healthcare Informatics. The annual compound growth rate increased to 6.5 percent over the past five years.

The study, "Developments in Cancer Treatments, Market Dynamics, Patient Access and Value," found that the U.S. and the five largest European nations continue to spend the most in oncology, making up two-thirds of the total international market.

Even as the share of total medicine spending of oncologics increased only modestly, earlier diagnosis, longer treatment duration and increased effectiveness of drug therapies are contributing to rising levels of spending on medicines for cancer care, according to IMS.

Targeted therapies have dramatically increased their share of total global oncology spending, while at the same time, payers and national health systems have intensified their scrutiny of the value of these medicines relative to their incremental benefits over existing treatments, with cost effectiveness assessments frequently resulting in limited patient access to these drugs, according to IMS.

Access and reimbursement issues are likely to become more complicated in coming years as individual and combination oncology medicines address multiple cancer types and patient populations with varying dosage and clinical value.

"The increased prevalence of most cancers, earlier treatment initiation, new medicines and improved outcomes are all contributing to the greater demand for oncology therapeutics around the world," said Murray Aitken, IMS Health senior vice president and executive director of the IMS Institute for Healthcare Informatics.

"Innovative therapeutic classes, combination therapies and the use of biomarkers will change the landscape over the next several years, holding out the promise of substantial improvements in survival with lower toxicity for cancer patients."

The report's key findings include:

Global oncology market continues to experience steady growth.

The global market for oncology drugs, including those used in supportive care increased 10.3 percent

in 2014 and reached \$100 billion, up from \$75 billion five years earlier. The compound annual growth rate in spending over the past five years has been 6.5 percent globally on a constant exchange rate basis.

Growth in the U.S. has risen more slowly at 5.3 percent CAGR, reaching \$42.4 billion in 2014. Oncology drug spending has risen slightly as a percentage of total drug spending over the past five years in all regions, most notably in the EU5 countries where oncology now represents 14.7 percent of total drug spending, up from 13.3 percent in 2010.

Within the U.S., the increase has been more modest, rising to 11.3 percent from 10.7 percent over the same period. Targeted therapies now account for nearly 50 percent of total spending and have been growing at 14.6 percent CAGR since 2009.

Clinical outcomes are improving for major cancers.

In most instances, five-year survival rates have risen through continuous and small improvements in detection and treatment—including refinements with existing treatments and gains from new treatment options.

Within the U.S., two-thirds of Americans diagnosed with cancer now live at least five years, compared to just over half in 1990. The strong pipeline of medicines in clinical development include new "immuno-oncologics" that hold out the promise of improved survival with lower toxicity for some patients, as well as combination therapies that can address multiple pathways in a tumor, potentially leading to substantial increases in survival.

Additionally, therapeutic effectiveness in multiple genetic subpopulations is being improved through the use of real-world evidence from deep biomarker data linked to treatment information. Molecular diagnostics are rapidly transforming drug development and patient selection, but only one-third of new oncology drugs have an identified biomarker at time of launch.

Patient access to cancer drugs varies across all markets.

The availability of new oncology medicines varies widely across the major developed countries, with patients in Japan, Spain and South Korea having access in 2014 to fewer than half of the new cancer drugs launched globally in the prior five years.

In pharmerging markets, availability of newer targeted therapies remains low but is increasing. Even among wealthy countries, new drugs may not be reimbursed and, as a result, will only reach a very small number of patients. Average therapy treatment

costs per month have increased 39 percent in the U.S. over the past ten years in inflation-adjusted terms.

Over the same period, patient response rates have improved by 42 percent and treatment duration has increased 45 percent, reflecting improved survival rates. Within the U.S., patient out-of-pocket costs have risen sharply for intravenous cancer drugs, increasing 71 percent from 2012 to 2013, reflecting changes in plan designs and increased outpatient facility costs.

Patients are engaging social media and online networks throughout their cancer journey.

Public discussion boards, followed by Twitter, are the most dominant channels used by patients during their cancer journey as they proactively engage on a wide range of topics including conversations regarding treatment options and financial concerns.

In a six-month assessment of social media discussions related to prostate cancer, the most frequent topic of discussion was treatment options, followed by financial concerns.

The full version of the report, including a detailed description of the methodology, is available at www.theimsinstitute.org. The study was produced independently, without industry or government funding.

In Brief

Sotomayor Named Inaugural Director of GW Cancer Center

EDUARDO SOTOMAYOR was named inaugural director of the **GW Cancer Center**. He will also serve as a professor of medicine.

Sotomayor will serve as chief academic and clinical leader with responsibility and authority over all aspects of the GWCC, starting in July. The GWCC will incorporate all cancer-related activities, as well as serve as the platform for future development. One of his top priorities will be to attain NCI designation within the decade.

Prior to joining GWCC, Sotomayor served as the scientific director of the DeBartolo Family Personalized Medicine Institute at Moffitt Cancer Center. He also served as the Susan and John Sykes Endowed Chair of Hematologic Malignancies and chair of the Department of Malignant Hematology at the Moffitt Cancer Center and Research Institute, as well as professor in the Department of Oncologic

Sciences and the Department of Pathology and Cell Biology at the University of South Florida College of Medicine.

His primary area of research is immunobiology and immunotherapy of B-cell malignancies, with emphasis on the design of novel immunotherapeutic approaches for these diseases. Clinically, Sotomayor has a particular interest in mantle cell lymphoma.

He has received the Lymphoma Research Foundation Fellowship Award and Junior Faculty Award, the Celgene's Young Investigator Achievement Award in Hematology, as well as continued research project grant funding during the past 15 years from NIH to support his basic and translational studies in cancer immunology and immunotherapy.

Sotomayor is a member of several committees, including Subcommittee A of the NCI, which is charged with reviewing the performance of all NCI-designated Cancer Centers. He is also a member of the executive committee of the Mantle Cell Lymphoma Consortium and the advisory board of the Lymphoma Research Foundation.

LISA KACHNIC was named professor and chair of the Department of Radiation Oncology at **Vanderbilt-Ingram Cancer Center**. She will join the faculty on Sept. 21.

Kachnic serves as professor and chair of Radiation Oncology and associate director of Multidisciplinary Cancer Research at Boston University School of Medicine, and chief of Radiation Oncology at Boston Medical Center.

Kachnic, who also serves on the Radiation Oncology faculty at Massachusetts General Hospital and is a fellow of the American Society for Therapeutic Radiology and Oncology, will succeed Arnold Malcolm, who retired from the position in December 2014.

Her primary areas of clinical interest include gastrointestinal malignancies, image-guided radiation delivery and outcomes and symptoms management research. She is internationally recognized for her clinical trial leadership positions in NCI and its cooperative group research bases. Kachnic is actively involved in the NRG Oncology gastrointestinal and patient-reported outcome strategic committees, and is the co-chair of their NCI Community Oncology Research Program in Cancer Control and Prevention. She is vice-chair of the NCI Anorectal Cancer Taskforce and co-chair of the anorectal committee for SWOG, where she also serves as their multi-modality executive officer.

In addition to serving as Scientific Committee vicechair and editor of ASTRO's newsletter, she belongs to a number of other professional organizations including the American Society of Clinical Oncology, where she chaired the group's 2014 GI meeting and is a member of their annual meeting's scientific program committee, and serves on the editorial boards of the Journal of the NCI and Gastrointestinal Cancer Research.

MD ANDERSON CANCER CENTER made several changes in its executive team.

Tadd Pullin was named senior vice president for institutional advancement. Starting in July, Pullin will lead marketing, communications, development, corporate alliances, the Children's Art Project and volunteer services. Tadd will be a member of MD Anderson's Executive Committee. Previously, Pullin served as senior vice president of marketing and strategy development at Nebraska Medicine.

Rebecca Kaul will serve as vice president and chief innovation officer, and will work with Information Services, Hospital and Clinic Operations, Strategic Industry Ventures, faculty and leadership. Kaul will also join the executive team in July.

Kaul comes to MD Anderson from the University of Pittsburgh Medical Center, where she served as chief innovation officer and president of the Technology Development Center. Previously, she served as president of A-Life Hospital and was co-founder and president of her own consulting firm.

Dan Fontaine was named executive vice president for administration. Fontaine served as executive chief of staff at MD Anderson and led the Institutional Advancement team.

In a letter, MD Anderson President Ronald DePinho said, "With Tadd joining in July, I've asked Dan to shift focus by continuing to provide oversight for business development (Global Business Development, Strategic Industry Ventures, Physicians Network and MD Anderson Services Corp.), regulatory affairs (Legal, Compliance, Internal Audit, Information Security and Police) and, additionally, provide executive oversight of Human Resources and Facilities."

Leon Leach, previously chief business officer at MD Anderson, will serve as executive vice president for strategy and innovation.

Leach, who served as chief business officer for more than 17 years, will continue to oversee Information Technology and help Kaul establish an MD Anderson innovation center. Leach will continue to serve as chairman of the Alliance of Dedicated Cancer Centers. **Weldon Gage** will be promoted to senior vice president and chief financial officer, effective Sept. 1.

Gage was named vice president and chief financial officer of MD Anderson Jan. 12. He began as a financial analyst at MD Anderson in 1999 and rose to associate director of strategic finance before accepting a position at Texas Children's Hospital, where he served from 2005 to 2012. In 2012, Gage left TCH as vice president for finance and joined Children's Hospital of Wisconsin as the organization's chief financial officer.

MICHAEL SIMON received the 2015 Blue Cross Blue Shield of Michigan Foundation McDevitt Excellence in Research Award for Physicians in the area of clinical research. Simon is leader of the Breast Cancer Multidisciplinary Team and co-leader of the Population Studies and Disparities Research Program at the Barbara Ann Karmanos Cancer Institute.

The award was given for his investigation into mammography use and the rates of breast cancer mortality in women 75 years and older. The award provides \$10,000 to be used for clinical or health policy research.

Simon and fellow scientists published this work in Breast Cancer Research and Treatment in 2014. The article is titled, "Mammography interval and breast cancer mortality in women over the age of 75." Study results suggested that the longer the time between diagnosis and the last self-reported mammogram was associated with higher rates of mortality due to either breast cancer or any cause of death.

The research represents a collaboration between Simon and researchers from the Albert Einstein College of Medicine, the University of Arizona Cancer Center; Fred Hutchinson Cancer Research Center; the University of California in Irvine; the Washington Cancer Institute and MedStar Washington Hospital Center; Stony Brook University School of Medicine; and the University of Pittsburgh.

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ERIC LIU, a surgeon specializing in neuroendocrine tumors, will join Rocky Mountain Cancer Centers June 1.

Liu comes to Rocky Mountain Cancer Centers from Vanderbilt University, where he established a neuroendocrine center. He also serves as the chief medical advisor for the Healing NET Foundation.

He and medical oncologist Allen Cohn, also from Rocky Mountain Cancer Centers, will head up a new Neuroendocrine Tumor Center in conjunction with HealthONE's Presbyterian/St. Luke's Medical Center.

THE MARYLAND PROTON THERAPY CENTER completed its funding, through parties including Varian Medical Systems, Deutsche Bank AG, and several private investors.

Varian has committed to loan up to \$35 million to the project through its subsidiary in Switzerland. Varian's commitment is in the form of a subordinated loan that is due, with accrued interest, in three annual payments from 2020 to 2022.

This year, Varian will book an approximately \$87 million order to equip MPTC with its ProBeam system. Varian has also signed a 10-year service agreement valued at approximately \$65 million.

The MPTC is being developed in Baltimore through collaboration between the University of Maryland Radiation Oncology Associates, P.A.; University of Maryland Medical Center; and Advanced Particle Therapy of Nevada. The MPTC is aiming to treat its first patient before the end of 2015.

<u>Drugs and Targets</u> Fast Track Designation Granted

To Merck's Evofosfamide FDA granted a Fast Track Designation

for evofosfamide (previously known as TH-302), administered in combination with gemcitabine, for the treatment of previously untreated patients with metastatic or locally advanced unresectable pancreatic cancer.

Evofosfamide is an investigational hypoxiaactivated prodrug thought to be activated under severe tumor hypoxic conditions, a feature of many solid tumors. The compound, currently in phase III trials, is being developed by Merck in collaboration with Threshold Pharmaceuticals Inc.

"Many patients with pancreatic cancer present with advanced, inoperable tumors, and there are limited treatment options currently available for them. The Fast Track designation for evofosfamide in pancreatic cancer—the second indication for this compound to receive Fast Track designation from the FDA, following the granting of the designation in soft tissue sarcoma [in November 2014]—will help to facilitate the timely development of this high-priority program for Merck Serono," said Luciano Rossetti, head of global research and development of Merck's biopharmaceutical business, Merck Serono.

Eli Lilly and Company and BioNTech AG entered into a research collaboration to discover novel cancer immunotherapies.

Lilly and BioNTech will work to identify and validate novel tumor targets and their corresponding T cell receptors in one or more types of cancer. These tumor targets and TCRs may then be engineered and developed into selective cancer therapies.

Under the terms of the agreement, BioNTech will receive a \$30 million signing fee. For each potential medicine, BioNTech could receive over \$300 million in development, regulatory and commercial milestones.

If successfully commercialized, BioNTech would also be eligible for tiered royalty payments. In addition, subject to the terms of the agreement, Lilly will make a \$30 million equity investment in BioNTech's subsidiary, Cell & Gene Therapies GmbH, which specializes in the research and development of TCR and chimeric antigen receptor immunotherapeutics. Further financial terms were not disclosed.

FDA approved the cobas KRAS Mutation Test for diagnostic use.

The real-time PCR test, developed by Roche, is designed to identify KRAS mutations in tumor samples from metastatic colorectal cancer patients and aid clinicians in determining a therapeutic path for them.

The test is a TaqMelt assay; a PCR-based diagnostic test intended for the detection of mutations in codons 12 and 13 of the KRAS gene. The test can be performed in less than eight hours.

The test is performed on the cobas 4800 System. The system includes the cobas BRAF V600 Mutation Test and EGFR Mutation Test.

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