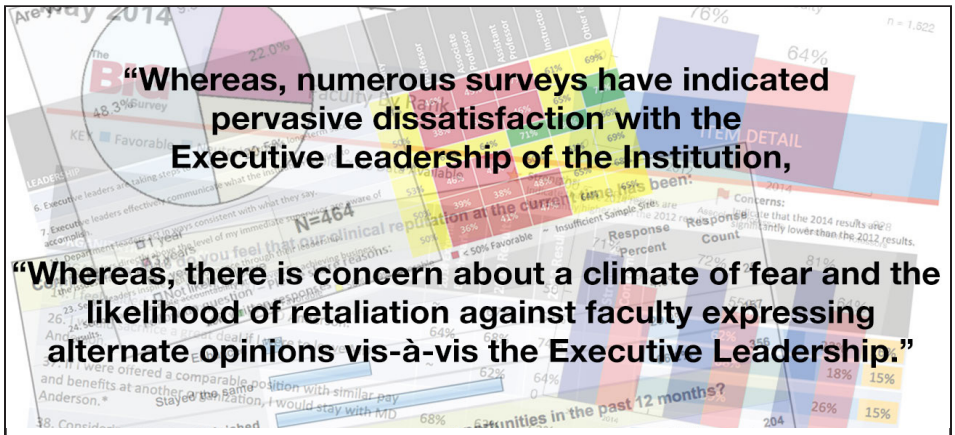
THE CANCER LETTER

Feb. 20, 2015 • www.cancerletter.com • Vol. 41 No. 7



Fix MD Anderson's Woes, Faculty Urges UT System

By Paul Goldberg

The Faculty Senate of MD Anderson Cancer Center asked UT System officials and the Board of Regents to "provide guidance" to the administration of the Houston-based center "in establishing milestones and timelines to implement measures to improve the morale of the faculty and the general health of the Institution."

The resolution, which was distributed to faculty Feb. 16, reveals that the faculty's dissatisfaction with MD Anderson President Ronald DePinho continues even after top UT System officials put him on notice to improve the faculty's morale (The Cancer Letter, Nov. 7, 2014).

(Continued to page 2)

ASCO's Multi-Million Big Data Project Aspires to be the "Bedrock" of Oncology

By Matthew Bin Han Ong

The CancerLinQ database of electronic health records is going through testing at 15 practices, and will be made available for research projects later this year.

The database, launched and operated by the American Society of Clinical Oncology, was designed to pool millions of physician and patient records from practices and hospitals.

(Continued to page 6)

In Brief

Theodore Lawrence Named Director Of University of Michigan Cancer Center

THEODORE LAWRENCE was named the director of the **University of Michigan Comprehensive Cancer Center**. He succeeds Max Wicha, who founded the cancer center 27 years ago. Lawrence will continue to serve as chair of radiation oncology.

(Continued to page 12)

MD Anderson Woes
Issue Brewing Since November 2014
. . . Page 2

Three Former Chairs of The Faculty Senate Start Petition
. . . Page 5

Conversation with TCL
ASCO CEO Allen Lichter Discusses CancerLinQ Big Data Project
. . . Page 8

In Brief
Karen Knudsen Named Interim Director at Sidney Kimmel Cancer Center
. . . Page 12

Funding Opportunity
PhRMA Launches Web Portal for Grants
. . . Page 13

Drugs and Targets
FDA Approves Lenvima In Thyroid Cancer
. . . Page 14

Fix MD Anderson's Woes, Faculty Urges UT System

(Continued from page 1)

The document asks the UT System to step in, but stops short of expressing a lack of confidence and doesn't seek removal of DePinho, who took the top job at the cancer center on Sept. 1, 2011.

"We were surprised to learn of the Faculty Senate's resolution of Nov. 20, 2014, since goals have been established and milestones reached in response to faculty concerns," a group of top administrators responded in a joint statement.

UT System officials said they are working with all sides.

"We are continuing to work closely with both the Executive Committee of the Faculty Senate and the executive leadership team of UT MD Anderson Cancer Center to foster a spirit of cooperative engagement," Ray Greenberg, the UT System executive vice chancellor for health affairs, said in a statement. "We are pleased that both groups are committed to working together in a collegial and constructive manner."

The resolution was passed unanimously by the 154 members of the MD Anderson Faculty Senate present at the Nov. 20, 2014, meeting. The resolution and an accompanying letter were sent to the regents on Feb. 6, in advance of their meeting Feb. 11-12.

The text of the resolution follows:

Whereas, numerous surveys have indicated pervasive dissatisfaction with the Executive Leadership of the Institution,

Whereas, there is broad dissatisfaction with the long term institutional priorities established by the Executive Leadership,

Whereas, there is consensus among faculty of a disenfranchisement in institutional governance,

Whereas, there is the lack of integration of existing faculty with new initiatives,

Whereas, there is an unbalanced financial support for long term initiatives at the expense of immediate clinical and research faculty needs,

Whereas, there is concern about a climate of fear and the likelihood of retaliation against faculty expressing alternate opinions vis-à-vis the Executive Leadership,

Whereas, there is an immediate concern that our highly esteemed faculty will continue to separate from the institution under the current circumstances,

The faculty of MDACC request that the Chancellor and Executive Vice Chancellor for Health Affairs, in close collaboration with the University of Texas Board of Regents, provide guidance to the Executive Leadership in establishing milestones and timelines to implement measures to improve the morale of the faculty and the general health of the Institution.

The Issue Was Brewing Since November 2014

The executive committee of the MD Anderson Faculty Senate sent the resolution to the UT System Board of Regents through Chancellor William McRaven and Executive Vice Chancellor for Health Affairs Raymond Greenberg.

A letter that accompanies the resolution described months of negotiations, during which Greenberg and former chancellor Francisco Cigarroa urged the MD Anderson faculty representatives to refrain from seeking a no-confidence vote, arguing that a confrontational stance would be "counterproductive," the letter states.

The text of the executive committee's letter to the regents follows:

The MD Anderson Cancer Center is one of the premier cancer hospitals and research centers in the world. Its preeminence has been achieved by the dedication of its leaders and outstanding faculty throughout its history.

However, over the last several years, a number of surveys have been conducted indicating a widespread dissatisfaction among the faculty with the leadership of MD Anderson's current President, Dr. Ronald DePinho.

The latest of these survey conducted by the UT System (Fall 2014) was consistent with the previous surveys, and if anything, represented a continuing decline in faculty morale. Upon being notified of the results of this survey, there were numerous requests to

Editor & Publisher: Paul Goldberg
Associate Editor: Conor Hale
Reporter: Matthew Bin Han Ong

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

Subscription $405 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.

the Executive Committee of the Faculty Senate (ECFS) from faculty that a vote of no confidence in regard to the President should be held by the Faculty Senate.

The ECFS polled its membership and concluded that for the sake of the Institution, this vote should be discussed at the next Senate meeting, on November 20, 2014.

Prior to the Senate meeting, the ECFS leadership held a telephone conference with Drs. Cigarroa and Greenberg. Both the Chancellor and the Executive Vice Chancellor suggested that a vote of no confidence might be counterproductive at that time.

Given the great respect that the ECFS has for both Dr. Cigarroa and Dr. Greenberg, their advice was considered and ultimately accepted. However, it was clear to the ECFS that given the dissatisfaction of the faculty with the MDACC leadership that some indication of the faculty's opinions must be relayed to the Board of Regents.

In addition, the ECFS was quite aware that a motion for a vote of no confidence was likely to be put forward from the floor at the November Senate meeting.

To prevent such a vote from taking place, and to inform the Board of Regents about the grave concerns of our faculty, the resolution that accompanies this cover letter was proposed and was passed unanimously by the 154 Faculty Senators present at the November meeting. The ECFS believes that this resolution represents an unambiguous statement as to the lack of trust and declining approval with the executive leadership of our Institution.

We wish to emphasize to the Board of Regents that it is with only the greatest reluctance that we bring this matter to your attention. Nevertheless, the ECFS and the Senate have a fiduciary duty to represent and put forward the expressed views of our faculty.

"Confidential" E-mail to 1,700 Faculty Members

The text of the resolution and the cover letter to the regents were distributed to the MD Anderson faculty members at 5:24 p.m. Feb. 16. The email was distributed by Karen Fukawa, project manager at the Faculty Senate. It was marked confidential.

An hour later, heads of MD Anderson divisions and the institution's vice provost responded with a non-confrontational email that suggested that the administration is addressing the faculty's concerns. The letter wasn't signed by DePinho; his wife Lynda Chin, chair of Genomic Medicine and scientific director of the Institute for Applied Cancer Science; Ethan Dmitrovsky, the provost; or Tom Buchholz, physician-in-chief.

The text of the response follows:

As faculty leaders whose key responsibilities include enhancing the mission of MD Anderson by upholding our core values and achieving our goal to eliminate cancer, we read with interest and take seriously the most recent message from the Executive Committee of the Faculty Senate (ECFS) to UT System Chancellor McRaven and Executive Vice Chancellor for Health Affairs Greenberg.

The Feb. 6 ECFS memo and its accompanying Nov. 20, 2014, Faculty Senate resolution again emphasize the need for us to listen to all of our colleagues and to consider all viewpoints. We must work together to address issues of concern in a collegial manner, ensuring that we maintain and increase the institution's positive trajectory.

With that in mind, we appreciate and thank the faculty for being partners with us in making steady progress, including the recent approval of new resources dedicated to improving clinical faculty efficiency. We have had extensive engagement of faculty members throughout all of our clinical divisions and science departments in establishing our long-term strategic plan and improving our near-term responsiveness to challenges. For example, several important actions in response to faculty member feedback were detailed in a presidential memo on Dec. 8—subsequent to the Nov. 20 resolution referenced by the ECFS. Many initiatives already have achieved results; others will take months to years, and we look forward to working with all of you moving forward.

We remain committed to understanding the needs of our faculty and maintaining an environment for both personal and professional fulfillment in support of our mission. As part of that effort, we will continue to engage and collaborate directly with our faculty colleagues as well as representatives of the Faculty Senate and its executive committee.

Especially during this time of unique and unprecedented pressures for academic healthcare institutions, we stand together with the faculty and our administrative leaders to surface problems for attention and to smartly and aggressively implement the solutions necessary to remain the premier cancer center for patient care, research, prevention and education. With your help, involvement, and partnership, we will ensure a culture of sustained excellence.

Thank you,
Marshall E. Hicks, division head, Diagnostic Imaging
Stephen G. Swisher, division head, Surgery
Richard E. Champlin, division head, Cancer Medicine, ad interim
Stephen Hahn, division head, Radiation Oncology
Stanley R. Hamilton, division head, Pathology and Laboratory Medicine
Ernest Hawk, division head, Cancer Prevention and Population Sciences
Helen Piwnica-Worms, Vice Provost of Science
Thomas F. Rahlfs, division head, Anesthesiology and Critical Care, ad interim
Cindy L. Schwartz, division head, Pediatrics, ad interim
Barbara L. Summers, division head, Nursing
David J. Tweardy, division head, Internal Medicine

A day later, on Feb. 17, top MD Anderson administrators joined the division heads in making a stronger statement, this time to The Cancer Letter, arguing that goals have been established and milestones reached in response to faculty concerns.

The administration's statement reads:

We were surprised to learn of the Faculty Senate's resolution of November 20, 2014, since goals have been established and milestones reached in response to faculty concerns. Just yesterday, in a communication to all faculty, our division head leaders outlined several outstanding efforts that have taken place since November. Additionally on December 8, several other important actions were detailed in a presidential memo to our faculty.

During the past several months, leadership and faculty members have worked together to address faculty frustrations and opportunities for improvement. Based on their complexity, issues were addressed rapidly or identified for a process of repair over time. We've also succeeded in engaging hundreds of faculty at every level in charting MD Anderson's future through our strategic planning process, and we've directed executive actions to improve communication of financial processes, reduce bureaucracy, direct seed and bridge funding, and onboard additional staff to reduce workload — all in response to faculty feedback. In addition, our leadership team continuously has opened new lines of communication with our physicians and scientists. While many of MD Anderson's 1,700 faculty members do not share the senators' concerns, we believe our unwavering commitment to listen, communicate and act will continue to have a positive impact on our world-class faculty over the coming months and years.

We welcome the input and participation of our faculty, our Board of Visitors, The University of Texas System, and importantly, our patients and families in ensuring the success of MD Anderson and achievement of our mission. Our focus remains clear and our commitment to the institution's continued clinical and research excellence remains strong for the countless people who entrust their lives to us.

Ronald A. DePinho, President
Thomas Buchholz, Physician-in-Chief and Executive Vice President
Ethan Dmitrovsky, Provost and Executive Vice President
Leon Leach, Executive Vice President and Chief Business Officer
Dan Fontaine, Executive Chief of Staff
Marshall E. Hicks, Division Head, Diagnostic Imaging
Stephen G. Swisher, Division Head, Surgery
Richard E. Champlin, Division Head, Cancer Medicine, ad interim
Stephen Hahn, Division Head, Radiation Oncology
Stanley R. Hamilton, Division Head, Pathology and Laboratory Medicine
Ernest Hawk, Division Head, Cancer Prevention and Population Sciences
Helen Piwnica-Worms, Vice Provost of Science
Thomas F. Rahlfs, Division Head, Anesthesiology and Critical Care, ad interim
Cindy L. Schwartz, Division Head, Pediatrics, ad interim
Barbara L. Summers, Division Head, Nursing
David J. Tweardy, Division Head, Internal Medicine

Follow us on Twitter: @TheCancerLetter

Three Former Senate Chairs Start Petition

On Feb. 20, three past chairs of the Faculty Senate started a petition in support of the administration. The three now hold administrative positions.

The email, circulated by Jean-Bernard Durand [who served as Faculty Senate Chair 2012-2013, and now serves as medical director of the Cardiomyopathy Service], and co-signed by J. Jack Lee [Faculty Senate Chair 2004-2005; associate vice provost for quantitative research] and Paul Mansfield [Faculty Senate Chair 2003-2004; vice president of Acute Care Services at the Office of the Physician-in-Chief] reads:

After speaking with many faculty senators as well as faculty at large, we, as past chairs of the faculty senate, believe that a broader perspective of the faculty should be heard. It was conveyed to us that a number of senators believe that the Executive Committee of the Faculty Senate (ECFS) actions did not accurately reflect what they understood to have occurred in November 2014.

We also heard from many faculty members at large who believe it does not fully represent their true sentiments nor is it a comprehensive depiction of the current environment. Below, please find a petition that we hope you will consider signing that affirms our belief in this great institution and what it stands for.

The text of the proposed petition follows:

We the undersigned members of the faculty of The University of Texas MD Anderson Cancer Center have read with deep concern the Feb. 6 letter to The University of Texas Board of Regents and the associated Faculty Senate resolution released by the Executive Committee of the Faculty Senate (ECFS).

This action by the ECFS cannot be said to reflect the full feelings of the faculty at large, and was not in the best interest of this institution, the faculty, the staff, the Faculty Senate, and most importantly the people who entrust us with their lives today and those whom our research will help in the future.

The rapid and dramatic changes in healthcare and the medical research environment place many stresses on all of us regardless of the role we play within this institution. While we may disagree about the best way to eliminate cancer and approaches to delivering quality care in today's complex healthcare environment, we are all unified in our desire to do so.

We support continuing open, transparent and constructive dialogue between faculty and administration to fulfill our mission. We believe in this great institution; we chose to come here because of its mission and we choose to stay here because of its future.

Click on the link below if you would like to add your name to this petition. Please respond by Friday, March 6. We cannot guarantee your anonymity but will not proactively share the list of signatories without prior notice. http://mdanderson.co1.qualtrics.com/SE/?SID=SV_29q9Wl32bHmwvJz

Previous Surveys

Members of MD Anderson's faculty are an intensely watched cohort.

Over a bit more than two years, four separate surveys attempted to gauge the level of faculty morale and satisfaction at MD Anderson Cancer Center.

All produced similar results: faculty morale is low, and a large proportion of the faculty says the administration is tone-deaf to their needs.

The most recent survey—conducted by the UT System and reported on Nov. 3, 2014—allows comparison with the earlier efforts.

The MD Anderson Faculty Senate administered two recent surveys of the faculty (The Cancer Letter, Jan. 18, 2013, March 29, 2013, Sept. 20, 2013).

MD Anderson's administration attempted to accomplish the same task in its biennial BIG Survey of the faculty and staff (The Cancer Letter, May 23, 2014).

The MD Anderson administration has acknowledged that there is room for improvement, albeit with the caveat that academic medicine is an unhappy place these days (The Cancer Letter, Dec. 12, 2014).

The upcoming vote in the works now represents the Faculty Senate's rejection of the administration's assurances that the problem is (1) overstated and (2) being managed.

"Our latest data shows there's work to be done in establishing improved relationships and communications between leadership and faculty," MD Anderson officials said in response to questions from The Cancer Letter last December. "Our faculty retention success is exceptional," officials said. "The institution has one of the highest faculty retention rates among all UT System institutions. When it comes to employees, MD Anderson's success is due in great part to our efforts to hire and retain people who share our passion for our mission.

"The dedication to them is reflected in many ways, including our regular attempts to obtain their input and reactions so that we can continue to ensure the best for our patients and those who serve them."

The administration provided the following examples of its efforts to improve faculty morale:

• We've launched extensive efforts to get our leaders out of the office and into our clinics, labs and

other work settings to talk with faculty. They attend staff meetings and feedback sessions to listen to concerns and take those thoughts and ideas back to the rest of the administrative team.

• Engagement efforts were extensive throughout our recent strategic planning process. Communications took place face-to-face, through email and online.

• We have expanded the extent of our communications, especially in areas where faculty and staff have requested more information.

• In response to the most recent faculty survey data, we've asked department heads to gather additional information to help us react and respond.

• We're addressing some of the logistical frustrations voiced by faculty related to computer technology used as part of our business.

• In response to our faculty's request to receive more information about MD Anderson's finances, we're increasing the regularity and depth of detail of these communications.

• We're investigating what we can do to help staff manage the expanding regulatory requirements we face. We want to ensure we're operating efficiently, safely and effectively, while reducing as much time burden for staff as possible.

ASCO Big Data Project Aspires To be "Bedrock" of Oncology

(Continued from page 1)

The professional society is investing $15 million to $20 million per year in the project.

CancerLinQ is expected to use patient care data from these records to provide feedback and clinical decision support to care providers. When the system is completed, doctors will be able to receive personalized insights based on up-to-date findings.

The database would also be geared to answer research questions.

"We can envision a process where investigators will pose a question, and we'll apply for a set of reports relative to the question at hand," ASCO CEO Allen Lichter said to The Cancer Letter. "This would be, I would imagine, reviewed by some independent group, and for those proposals that are considered meritorious, a price will be set to cover our costs of pooling the data and doing the analysis, and we will be sending those reports on to the investigator.

"I expect that not every proposal will be considered meritorious, but we do feel that it's important to set a standard and a threshold for working with CancerLinQ data," Lichter said.

A conversation with Lichter appears on p. 8.

Work on CancerLinQ began in 2010, with an estimated budget of $80 million for the first five years. The funds are raised from philanthropy, ASCO's revenues, its foundation, advocacy organizations, and pharmaceutical companies (The Cancer Letter, Nov. 22, 2013).

Partnership with SAP

ASCO recently announced their collaboration with SAP SE (Systems, Applications & Products in Data Processing), a German multinational software corporation that makes enterprise software to manage business operations and customer relations. SAP's task is to structure CancerLinQ (The Cancer Letter, Jan. 23).

"We actually talked about hiring a software innovator and building this ourselves," Lichter said. "That was a very real consideration, but in the end, the recognition is that our skills inside ASCO are not in software development. Our skills are in understanding oncology, oncology quality, performance measures, and advancing the field forward."

SAP will be providing the financial resources to develop their product to meet the oncology use cases that the society is developing, said ASCO President Peter Yu during a press call Jan. 21.

"The division of labor kind of goes, 'So who's responsible for what?' ASCO, as the oncologists' side, is in a position to know best what cancer doctors, cancer patients, cancer researchers, and the whole cancer industry needs to have out of the data management," Yu said at a recent press conference. "So to that end, ASCO staff is charged with focusing on identifying the use cases, charged with identifying the products that we are not at liberty to talk about today, but actually, the products will really make everybody stand up and say, 'We need to have this and we need to have it now.'

"That will include things like decision support tools, both rules-based and probabilistic-based, as well as designing outcomes measures and specifying the data elements that will need to be tracked in a semantically correct manner to fuel the clinical decision support and research needs. Those remain the intellectual property of ASCO. I'm not at liberty to give you precise dollar counts, but we are talking about eight figures."

SAP's experience with developing cancer data analytics and genomic analysis will be valuable to CancerLinQ, Yu said.

"With SAP, when we were looking for partners, we know what our core strengths are, and we know what our

needs are, so who's a good partner that can, one, supply what we need, which is a technological platform, and who is willing to invest in the future development of that," Yu said. "And two, has enough knowledge about health care and experience in health care, but isn't going to say that they are the experts in oncology and we're going to have to sit down and negotiate everything.

"SAP really made us feel tremendously comfortable, knowing, as we explored the robustness of their HANA project. It's a mature project; it's in use in other industries; it's in use in several major health care systems.

"There's been work done in Germany, at the University of Heidelberg, on developing oncology use cases, and we spoke with the investigators there."

SAP has been investing heavily in health care in recent years, said David Delaney, chief medical officer of SAP America's health care business unit.

"When you look at some of the challenges of deep data mining, creating and understanding insights within the data, being able to do this all in real time—these are generic challenges that we have across the 25 sectors that SAP is present in," Delaney said. "And our R&D budget varies year to year, but you're talking a little shy of $3 billion annually, and much of that is focused on database technology and analytics.

"Generically, we are investing very heavily in this space, across sectors, and specifically in health care. We've been focused on some of the precision medicine challenges with the database and technology, specifically. And we've been investing in that for several years now. So there's already an ongoing investment, which this is a natural acceleration on.

"And then the last piece of the investment is particular to ASCO and CancerLinQ, because again, we see such tremendous value in the trust placed by the clinicians and cancer patients in ASCO. They are a trusted entity whom people will give their data to. They know great value and good will be created from it.

"There's that trust, which, really, at the end of the day will, in our minds, create a critical mass of data, which we can then use the tools on to create value. So I really think there are three different layers of investment that are going on there."

ASCO didn't release financial details of the partnership.

Potential Competitors

ASCO intends for CancerLinQ to become the go-to database for wide variety of oncology-related organizations: commercial, health insurance, biotechnology and pharmaceutical companies, and even FDA as well as other government agencies, the society's officials said.

"We view CancerLinQ as a critical component and see it over time as being the bedrock upon which practitioners perform high quality care, and that patients can rely on to assure themselves that they are receiving that care," Lichter said.

It remains to be seen how ASCO's participation will shape the market for oncology bioinformatics at a time when various players are capitalizing on electronic medical records.

In 2013, the completion of CancerLinQ's prototype included more than 170,000 de-identified medical records of breast cancer patients from oncology practices around the U.S.

Around the same time, another large provider of oncology-specific EMRs, Flatiron, announced that it had surpassed its 25 cancer center partners with a database of over 100,000 de-identified patients.

Another player is the Oncology Research Information Exchange Network, a research partnership founded by Moffitt Cancer Center in Tampa and The Ohio State University Comprehensive Cancer Center–Arthur G. James Cancer Hospital and Richard J. Solove Research Institute (The Cancer Letter, May 30, 2014).

ORIEN partners utilize a common protocol: Total Cancer Care. Established by Moffitt in 2006, Total Cancer Care provides a standard system for tracking patient molecular, clinical and epidemiological data and follows the patient throughout his or her lifetime.

Partners have access to one of the world's largest clinically annotated cancer tissue repositories and data from more than 100,000 patients who have consented to the donation for research.

Google-run Flatiron has two products: OncoAnalytics and OncologyCloud, which give oncologists and cancer care practices direct, customizable access to practice management and billing data, in addition to EMRs.

Another umbrella group, the National Comprehensive Cancer Network, which develops practice guidelines and pathways in oncology, is vying to expand its role as big data reshapes the field.

For-profit players, whose expertise covers at least some of the territory CancerLinQ would span, include the drug supplier McKesson, which has an alliance with NCCN to create clinical pathways and to produce software that will allow physicians to assess treatment options consistent with evidence-based standards.

The pathways and supporting software will also

allow providers to consult coverage policies mandated by payers (The Cancer Letter, Nov. 30, 2012).

The market for clinical pathways and decision support and review systems, one of the segments of CancerLinQ's activities, is competitive.

Players include the P4 Pathways, owned by CardinalHealth; Via Oncology Pathways; Eviti Inc.; ICORE Healthcare; and others.

Content libraries and software from these firms are used by a number of regional and national payers. IBM is also developing a decision support system using its Watson technology.

EMR Quality Assurance

CancerLinQ is run by a five-member Board of Governors and eight separate committees, including a Governance Oversight Committee, which is responsible for the quality of the data.

Comprehensive structuring of medical records comes with an extensive set of challenges: each hospital's filing and reporting system may be different, and records can have data elements that were either missed or accidentally omitted.

"We aren't going to sugarcoat the fact that, if you've looked at medical records, be they paper records, or electronic records, they are often far from pristine," Lichter said.

ASCO promises that the quality of data in CancerLinQ will improve over time.

"Mining that unstructured data to create detailed, structured elements is a challenge. We recognize all of this," Lichter said. "We have confidence that, as we begin to collect data and feed back information to practices, that places where the data is less than ideal will begin to improve in an iterative process, and over time, the quality of the data will get better and better."

Another ongoing ASCO project, TAPUR, or the Targeted Agent and Profiling Utilization Registry, will eventually be folded into CancerLinQ as the latter matures, and when it is able to support additional spinoffs.

TAPUR is designed to gather data from the off-label use of targeted cancer drugs in patients with advanced cancer whose tumor harbors a genomic abnormality.

"We envision, as the project gets going, that we will have a patient-facing side of CancerLinQ," Lichter said. "We will be collecting patient-reported outcomes over long periods of time to understand the impact of cancer treatment, and recovery from the patient's point of view."

ASCO: CancerLinQ Not For Profit

CancerLinQ will be generating revenues, but making money is not the project's primary purpose.

"The system has costs, and while ASCO has been willing to invest substantial resources in standing the system up, and will continue to invest resources, eventually, the program has to have a revenue stream in order to be sustainable over the long haul," Lichter said.

"In the end, we want to emphasize that we are not creating CancerLinQ for the purpose of producing revenue for ASCO.

"We're creating CancerLinQ to make cancer care better. The need for revenue is apparent, and has to be dealt with over time. But that is not our motivation."

As of Jan. 21, eight oncology practices around the U.S. have signed agreements with CancerLinQ to provide patient records for the first version of CancerLinQ, scheduled for release in late 2015. Seven more large cancer centers are expected to join the effort, meaning approximately 500,000 patients will be represented in CancerLinQ.

Those eight oncology practices are: Inova Comprehensive Cancer & Research Institute; South Coast Centers for Cancer Care; New England Cancer Specialists; Medical Oncology Hematology Consultants; Cancer Treatment Centers of America; Marin Cancer Care; Space Coast Cancer Center; and Michiana Hematology-Oncology P.C.

CancerLinQ is conceived, for now, as a stand-alone project.

"We control our own destiny, and so we can speak of ourselves," Lichter said. "But over time, yes, CancerLinQ will interface, work with, partner with numerous other organizations for the good of cancer patients."

Conversation with The Cancer Letter

ASCO CEO Allen Lichter Discusses CancerLinQ

Five years into the making of CancerLinQ, the American Society of Clinical Oncology is poised to become the next big player in oncology bioinformatics.

ASCO has enlisted the help of SAP, a large multinational corporation that specializes in enterprise software, to structure over 170,000 electronic medical records into a growing database that will be launched later this year.

Billed as a "physicians for physicians" product, CancerLinQ is expected to yield high quality data that only quality research proposals can access.

The Cancer Letter asked ASCO CEO Allen Lichter to describe the inner workings of CancerLinQ, and what sets it apart in a competitive EMR market.

"We believe that the quality of medical care is a physician responsibility," Lichter said. "Therefore, the quality of oncology care is the responsibility of the physician professionals who care for the patients.

"The professional society that organizes oncology physicians is ASCO. And therefore it's not a big leap to say this work is fundamental to ASCO, and to the field of oncology. The quality of cancer care is something that the profession has to take ownership of."

Lichter spoke with Matthew Ong, a reporter with The Cancer Letter.

Matthew Ong: *What is CancerLinQ's business model? Is it for profit, and who are CancerLinQ's target consumers?*

Allen Lichter: Practices will use this system to monitor the quality of their care, understand their practice better from an administrative perspective, and together we will gain new insights from the aggregated data to make care better and more personalized.

CancerLinQ remains inside ASCO, which is a nonprofit organization run by physicians for physicians. This is one of the things that distinguishes our offering from other data gathering offerings that are out there, or are proposed.

Having said that, the system has costs, and while ASCO has been willing to invest substantial resources in standing the system up, and will continue to invest resources, eventually, the program has to have a revenue stream in order to be sustainable over the long haul.

There are a variety of ways that one can imagine revenue coming in through CancerLinQ. We have, of course, philanthropic donations that come in to support this critically important project and we expect that will continue.

We have the ability to apply for grant funding for contracts from organizations that might be interested in the data. For example, if the FDA would be interested in having reports about safety signals that we see, or if PCORI, the Patient-Centered Outcomes Research Institute, has interest in comparative effectiveness and those reports might come from us, one could see contract or grant funding coming our way.

We expect researchers will be looking for data from us to answer important clinical research questions, and we expect fees to be associated with us producing those data cuts, and there can be reports that commercial companies are interested in. Examples include health insurance companies or pharmaceutical and manufacturers interested in reports about drug utilization, drug safety and so forth.

There are potentially a broad amount of revenue opportunities. How these will play out over time remains to be seen.

In the end, we want to emphasize that we are not creating CancerLinQ for the purpose of producing revenue for ASCO. We're creating CancerLinQ to make cancer care better. The need for revenue is apparent, and has to be dealt with over time. But that is not our motivation.

MO: *All these different groups will have access to CancerLinQ, and can essentially buy data for research purposes?*

AL: People who have research proposals build in funding inside those proposals for data. Researchers are used to having some data acquisition cost built into their expenses, as are commercial companies.

MO: *What is ASCO's budget for CancerLinQ? How much does an extensive project like this cost?*

AL: At this point, we estimate that we will be spending between $15 and $20 million a year as the program expands and reaches maturity. It could even go higher than that, and some of our sister societies, in their quality registry programs, spend even higher sums, so it is not inconsequential.

The costs are associated with the platform itself: maintaining it, improving it, running it, et cetera. This is a large-scale project, and the staffing—software engineers, informaticists, biostatisticians, the privacy and security experts, the data stewards—the fully-mature project will need them to keep it going and to keep the integrity of the data, as it should be kept. This is far from an inexpensive project, but it is one that is well worth it.

MO: *How accessible and easily usable will the data be? And how will ASCO maintain the quality of the data?*

AL: We have a data governance committee made of outstanding experts in the field of oncology data—privacy and security, patient advocates, and others who help set the policies for how data can be accessed and what our processes will be.

Since we have not started to collect data, these policies are not finalized and firmed up, but they are being created now.

We can envision a process where investigators will pose a question, and apply for a set of reports relative to the question at hand. This would be, I would

imagine, reviewed by some independent group, and for those proposals that are considered meritorious, a price will be set to cover our costs of pooling the data and doing the analysis, and we will be sending those reports on to the investigator.

I expect that not every proposal will be considered meritorious, but we do feel that it's important to set a standard and a threshold for working with CancerLinQ data.

We expect the quality of the data, over time, to be extremely high. We aren't going to sugarcoat the fact that, if you've looked at medical records, be they paper records, or electronic records, they are often far from pristine.

There are missing data elements. There are sometimes errors that propagate through a medical record, especially as people cut and paste from one encounter to the next, which we know often happens. There's a large amount of important data tied up in unstructured reports—physicians' and nurses' notes, radiology and pathology reports, et cetera.

Mining that unstructured data to create detailed, structured elements is a challenge. We recognize all of this. We have confidence that, as we begin to collect data and feed back information to practices, that places where the data is less than ideal will begin to improve in an iterative process, and over time, the quality of the data will get better and better.

At the same time, we will have lots and lots of data, and there are times where a missing piece of data in a small clinical trial can be vital, but the same missing data, if you were analyzing a dataset of 10,000 or 50,000 patients may be much less impactful.

The character of these discussions changes when one starts dealing with very large datasets.

MO: *Speaking of structuring data, why did ASCO choose SAP? What makes SAP uniquely qualified for CancerLinQ amid many companies who have experience with EMRs and oncology?*

AL: SAP is the largest provider of enterprise software in the world. The vast majority of the largest companies and organizations on the planet run SAP software. They estimate that over 70 percent of the world's GDP transactions flow through SAP software.

Their reputation for creating and handling large volumes of data in an extremely secure fashion for providing software analytic tools that work in the real world is very strong.

They are a large and established company that can devote a number of years necessary to a project like this, to make the project truly effective. So after looking at a number of different choices with great care, it was the conclusion of our board that SAP represented the best organization to work with to invent this system, and we are thrilled that they are working with us.

We actually talked about hiring a software innovator and building this ourselves. That was a very real consideration, but in the end, the recognition is that our skills inside ASCO are not in software development. Our skills are in understanding oncology, oncology quality, performance measures, and advancing the field forward.

MO: *What is the status of ASCO's conversations with SAP?*

AL: We've already had three week-long workshops with the extensive SAP team that's working on this, most recently spending time with about 15 physicians from practices that have agreed to be the early adopters of the program.

We have said over and over again that this program is going to be created by physicians for physicians, with the goal of improving the quality of cancer care on behalf of our patients, and we are seeing that play out right now in real time.

MO: *How is CancerLinQ different from other databases? What does CancerLinQ bring to oncology that others do not have?*

AL: We believe that the quality of medical care is a physician responsibility. This is at the core of the practice of medicine, and what makes medicine a profession. Therefore, the quality of oncology care is the responsibility of the physician professionals who care for the patients.

The professional society that organizes oncology physicians is ASCO. And therefore, it's not a big leap to say this work is fundamental to ASCO, and to the field of oncology.

The surgeons have done quality work in a broad variety of areas for decades, including the Commission on Cancer. That's an example of a professional organization that has said the quality of care and specifically the quality of cancer care is something that the profession has to take ownership of. And we're doing this specifically inside medical oncology, in the case of ASCO.

MO: *What will happen to ASCO's TAPUR [Targeted Agent and Profiling Utilization Registry]?*

AL: TAPUR is a project that is designed to gather real-world data about the use of targeted agents in off-label situations. The fact is, if CancerLinQ was running right now, the TAPUR project would be a piece of CancerLinQ, because the data collection would be

occurring inside CancerLinQ, just by matter of design.

We've had to call out TAPUR as a specific standalone project because we don't have CancerLinQ running right now, so we had to create a project that's an end-to-end project that has all the pieces, including the data collection as part of the project.

But once CancerLinQ stands up, the TAPUR project literally will fold into it, as one of the offshoots of CancerLinQ. And there will be other projects that will be a spinoff or part of CancerLinQ.

For example, we envision, as the project gets going, that we will have a patient-facing side of CancerLinQ. We will be collecting patient-reported outcomes over long periods of time to understand the impact of cancer treatment, and recovery from the patient's point of view. We will be able to exchange information back and forth with patients. Clinical decision support will become a part of CancerLinQ so that we begin to build quality assessment into the process of care—while it's occurring—versus monitoring after it has already taken place.

MO: *Speaking of other projects, will CancerLinQ be a standalone ASCO project, or does ASCO have any plans to collaborate with other groups who are also building databases?*

AL: We've conceived it right now, of course, as a standalone. However, if one is interested in the quality of cancer care from a patient point of view, it's not simply the quality of the medical oncology care that the patient receives that is determinative.

The patient has a journey that starts with the diagnosis, so the pathology has to be done correctly. The laboratory tests and markers, and molecular workup has to be done appropriately. The radiology imaging workup has to be done and interpreted appropriately. Then there could be surgery, the radiation, as well as the chemotherapy, and then the rehabilitation to return the patient back to full productivity.

All of those steps are important, and we have had discussions with the pathologists, the radiologists, the radiation oncologists, and surgeons, to begin to talk about, over time, how different approaches to quality can be merged together so that we can make sure that patient care, from start to finish, is of the highest standards.

We can't boil the ocean in an afternoon, and so some of these plans at this point are aspirational, and it's important for us to stand up CancerLinQ and to make sure that it adds value from the standpoint of the physicians and practices who use it. That is our primary goal right now.

But over time, yes, CancerLinQ will interface, work with, partner with numerous other organizations for the good of cancer patients.

MO: *How is ASCO engaging patients, physicians and hospitals right now to develop CancerLinQ?*

AL: From the physician side, we have created a group of 15 practices—we're calling them the "vanguard" practices—who will have the first access to CancerLinQ. They will be part of designing it; they will be part of giving us feedback so that we can continue to improve the project.

It is inappropriate for us to design CancerLinQ back in the office and then release it to the world and then hope for the best. We've seen big data and big software projects do that and crash and burn, and that is not our intention.

So the access to CancerLinQ, to begin with, will be limited until we are confident that the program functions well and adds value the way we hope it does.

Once that happens, we will begin to scale it and bring other practices and other sites in. How fast that happens is simply a matter of how well we have designed and implemented it, and how we can modify it and incorporate the inevitable improvements as it gets used.

On the patient side, we have a patient committee involved in ASCO. In the end, CancerLinQ takes patient data, aggregates it, and uses it to improve the quality of care. Patients are integral to this, and we are listening to them from day one, and will continue to have them heavily involved in the project.

MO: *Where do you see CancerLinQ five, 10, or even 15 years from now?*

AL: The practice of oncology is becoming increasingly complex with new drugs, new targets, new subsets of patients. It is becoming increasingly difficult for any oncology physician to keep all of this in their head. Unless you are a subspecialist concentrating on a narrow sliver of disease, that pace of change is coming too fast.

We view CancerLinQ as a critical component and see it over time as being the bedrock upon which practitioners perform high quality care, and that patients can rely on to assure themselves that they are receiving that care.

We envision a time when practitioners will have their EMR running, and CancerLinQ running, using both systems to help extract information and knowledge to aid in decision support allowing physicians, really, for the first time, to have the expertise of the entire field directly in front of them, a few key strokes away.

We're quite excited about this. As I mentioned at the outset, we think this is our responsibility. We take that responsibility extremely seriously and are anxious to bring this project forward.

We will have a demonstration available by the time of the annual meeting, so our colleagues can begin to see and feel and touch what this will look like as it rolls out, and we are as excited and enthusiastic as we could possibly be about the future.

In Brief

Lawrence Named Director Of UMich Cancer Center

(Continued from page 1)

Lawrence's research interests are focused on chemotherapeutic and molecularly targeted radiosensitizers. His research uses conformal radiation guided by metabolic and functional imaging to treat patients with pancreatic and other gastrointestinal cancers. Lawrence expects to continue patient care and research activities while serving as director.

He plans to grow the center's statewide presence as part of an effort to make cancer care more local. "The vast majority of cancer care can be done in the community with strong partnerships. We want to create more of those partnerships to allow more patients in our state to receive the right care in the right place," Lawrence said.

Lawrence has served in leadership positions in the American Society of Radiation Oncology, the American Society of Clinical Oncology, the Radiation Oncology Institute, the Society of Chairs of Radiation Oncology, and both the Board of Scientific Councilors and the Board of Scientific Advisors of the NCI, among others. He is a member of the Institute of Medicine of the National Academy of Sciences. He has received the ASTRO Gold Medal, an ASCO Statesman Award, and the 2014 Outstanding Investigator Award from the Radiological Society of North America.

KAREN KNUDSEN was named interim director of the **Sidney Kimmel Cancer Center** and interim chair of the Department of Cancer Biology at Thomas Jefferson University.

Previously, Knudsen was vice provost for the university, overseeing basic and clinical research across all six schools. She was also leader of the Prostate Program at SKCC, and deputy director for research.

Knudsen is a Hilary Koprowski Endowed Professor and a professor in the departments of Cancer Biology, Urology, Radiation Oncology and Medical Oncology. She leads a research group that focuses on prostate cancer.

Knudsen has received numerous awards, including the Richard E. Weitzman Laureate Award from the Endocrine Society, the Ronald Ross Award for Excellence in hormone-dependent malignancies from the Pacific Rim Breast and Prostate Cancer Research Organization, and most recently, the SWIU/Society for Basic Urologic Research Award for Excellence in Urologic Research.

She was a senior editor for Cancer Research from 2007 to 2013, is an advisory editor for Endocrine-Related Cancer, and sits on the editorial boards of Molecular Cancer Therapeutics, the American Journal of Pathology, and Oncogene. In 2014, Dr. Knudsen was appointed editor-in-chief of Molecular Cancer Research by AACR.

JONATHAN JAROW was named acting director of the Office of Medical Policy in the **FDA Center for Drug Evaluation and Research**.

Jarow will serve a 120-day detail as acting director, beginning Feb. 23. He will replace Denise Hinton, who served as acting OMP director for the past 13 months. Hinton will resume her position as deputy director.

Jarow currently serves as associate director of the Office of Hematology and Oncology Products, and previously served as acting deputy director of OHOP. He has developed policies for management of neoplasm imbalance review in conjunction with the Office of Surveillance and Epidemiology, biostatistics, and pharmacologic toxicology. He also supervises the Oncology Program and organizes educational programs for review staff.

He also serves as a team leader for the Clinical Trials Transformation Initiative project regarding IND safety reporting regulations. He helped create the Scientific Liaisons, interdivision rotation of medical officers, and a memorandum of understanding with NIH for hiring medical officers who will divide their time between NIH and FDA.

He has led a cross-center working group that includes participants from CDER, CDRH, and CBER to create uniform policies for the development of medical products for the management of localized genitourinary malignancies. This group has organized three public workshops, authored three publications, and has a guidance for development of bladder cancer treatments under development.

Jarow has also held medical officer positions in the Division of Oncology Products 1 and the Division of Reproductive and Urology Products, now the Division of Bone, Reproductive and Urologic Products.

THE AMERICAN ASSOCIATION FOR CANCER RESEARCH announced 11 fellows of the AACR Academy.

All fellows are nominated and elected through a rigorous peer-review process conducted by existing fellows of the AACR Academy and ratified by the AACR Executive Committee. This process involves an assessment of each candidate on the basis of his or her scientific achievements in cancer research and cancer-related biomedical science.

The AACR will formally induct its class of elected fellows at its 2015 annual meeting, in Philadelphia, April 18-22.

Members of the 2015 class of fellows of the AACR Academy are:

• **Kenneth Anderson**, director of the Jerome Lipper Multiple Myeloma Center and LeBow Institute for Myeloma Therapeutics at the Dana-Farber Cancer Institute

• **Carlos Arteaga**, director of the Center for Cancer Targeted Therapies; director of the Breast Cancer Program; and associate director for Clinical Research at Vanderbilt-Ingram Cancer Center

• **Anton J.M. Berns**, senior group leader in the Division of Molecular Genetics at the Netherlands Cancer Institute; and director of the Skoltech Center for Stem Cell Research in Moscow

• **Bruce Chabner**, director of clinical research at Massachusetts General Hospital

• **Ronald DePinho**, president of MD Anderson Cancer Center

• **Susan Desmond-Hellmann**, CEO of the Bill & Melinda Gates Foundation

• **Robert Eisenman**, member of the Division of Basic Sciences at Fred Hutchinson Cancer Research Center

• **Douglas Lowy**, deputy director of the Center for Cancer Research; chief of the Laboratory of Cellular Oncology; and head of the Signaling and Oncogenesis Section at NCI

• **Carol Prives**, Da Costa professor at Columbia University

• **Steven Rosenberg**, chief of surgery at NCI

• **Craig Thompson**, president and CEO of Memorial Sloan Kettering Cancer Center

VARIAN MEDICAL SYSTEMS was selected to equip and service a new national proton therapy center in Aarhus, Denmark, with the Varian ProBeam proton therapy system.

Under a completed public tender, Varian was selected to provide equipment, software and service to operate a four-room center for up to an estimated $70 million. Varian expects to conclude and sign the contract and book the equipment and software portion of the order in March.

In addition to the ProBeam system, Varian will provide its ARIA information management software. Equipment installation is expected to take place in mid-2017, with patient treatments expected to begin in the second half of 2018. The National Centre for Particle Therapy will be situated alongside Aarhus University Hospital in Denmark's second-largest city.

Funding Opportunity

PhRMA Launches Web Portal For Competitive Grants

The Pharmaceutical Research and Manufacturers of American Foundation launched a platform featuring resources on its competitive research grants and fellowships for young scientists.

The foundation awards more than $3.3 million annually to researchers with support from PhRMA's member companies. Recent grants have focused on topics such as comparative effectiveness, adherence improvement and health outcomes.

The foundation also plans to update the website later this year with educational modules developed in partnership with the NIH Clinical Center, the Foundation for the NIH, and the American Society for Clinical Pharmacology and Therapeutics. These resources for health care students and professionals will discuss topics such as safe and effective prescribing.

Drugs and Targets

FDA Approves Lenvima In Metastatic Thyroid Cancer

FDA approved Lenvima (lenvatinib) for the treatment of locally recurrent or metastatic, progressive, radioactive iodine-refractory differentiated thyroid cancer. Lenvima was approved following a priority review.

Lenvima demonstrated a statistically significant progression-free survival prolongation and response rate in patients with progressive, differentiated thyroid cancer who had become refractory to radioactive iodine therapy.

In the phase III SELECT trial, which included 392 patients, Lenvima demonstrated a highly statistically significant improvement in PFS in patients with RAI-R DTC compared with placebo. The median PFS with Lenvima and placebo was 18.3 months and 3.6 months, respectively (HR 0.21; 95% CI: 0.16-0.28; $p<0.001$).

In addition, an overall response rate of 65 percent was seen in patients treated with Lenvima versus 2 percent with placebo.

Lenvima is sponsored by Eisai Inc.

FDA expanded the existing indication for Revlimid (lenalidomide) in combination with dexamethasone to include patients newly diagnosed with multiple myeloma.

Revlimid plus dexamethasone was previously approved in June 2006 for use in multiple myeloma patients who have received at least one prior therapy.

The approval was based on safety and efficacy results from phase III studies, including the FIRST trial (MM-020/IFM 07-01), which evaluated continuous Revlimid in combination with dexamethasone until disease progression versus melphalan, prednisone and thalidomide for 18 months as the primary analysis, and a fixed duration of 18 cycles of Rd as a secondary analysis, in 1,623 newly diagnosed patients who were not candidates for stem cell transplant.

PFS was significantly longer for patients receiving Rd Continuous (25.5 months) than for those treated with MPT (21.2 months; HR=0.72; p=0.0001). Median overall survival in the two groups was 58.9 months and 48.5 months, respectively (HR 0.75; 95% CI 0.62, 0.90) based on a March 3, 2014 interim OS analysis. Patients in the Rd Continuous arm had a 25 percent reduction in the risk of death compared to patients in the MPT arm.

Revlimid is sponsored by Celgene Corporation.

FDA granted an Orphan Drug Designation to Saposin C, the active ingredient in drug BXQ-350, for the potential treatment of glioblastoma multiforme.

A successful application submitted by Bexion Pharmaceuticals, the drug's sponsor, would entitle the company to a seven-year period of marketing exclusivity in the U.S. for BXQ-350.

Bexion was previously awarded a Phase II Bridge Award SBIR Grant from NCI to support the manufacture and clinical testing of BXQ-350.

FDA granted an Orphan Drug Designation to antinuclear antibody conjugated liposomal doxorubicin, developed by NanoSmart Pharmaceuticals Inc., for the treatment of Ewing's sarcoma, a rare cancer that develops in or around children's bones.

The FDA grants orphan status to drug therapies for rare diseases that affect less than 200,000 persons in the U.S. Sponsor companies qualify for certain development incentives, such as fee waivers, tax credits, access to grant funding for clinical studies, and potential for a period of market exclusivity upon approval.

FDA granted an Orphan Drug Designation to Reolysin for the treatment of pancreatic cancer.

This is the second Orphan Drug Designation Reolysin has received; the other being for ovarian cancer. Reolysin is being developed by Oncolytics Biotech Inc.

Reolysin is Oncolytics' isolate of the reovirus. Its primary mode of activity is to infect and selectively target tumors with activating Ras pathway mutations and/or over-expressions of Ras pathway elements including, amongst others, EGFR, BRAF and KRAS.

The U.K. National Health Service established an access program for the Oncotype DX test, developed by Genomic Health Inc., for breast cancer patients, effective April 1.

The multi-gene breast cancer test was recently recommended by the National Institute for Health and Care Excellence for use as an option to assist in chemotherapy treatment decision-making. The program enables NHS hospitals to provide genomic testing to patients with early-stage, hormone receptor-positive, HER2 negative, invasive breast cancer.