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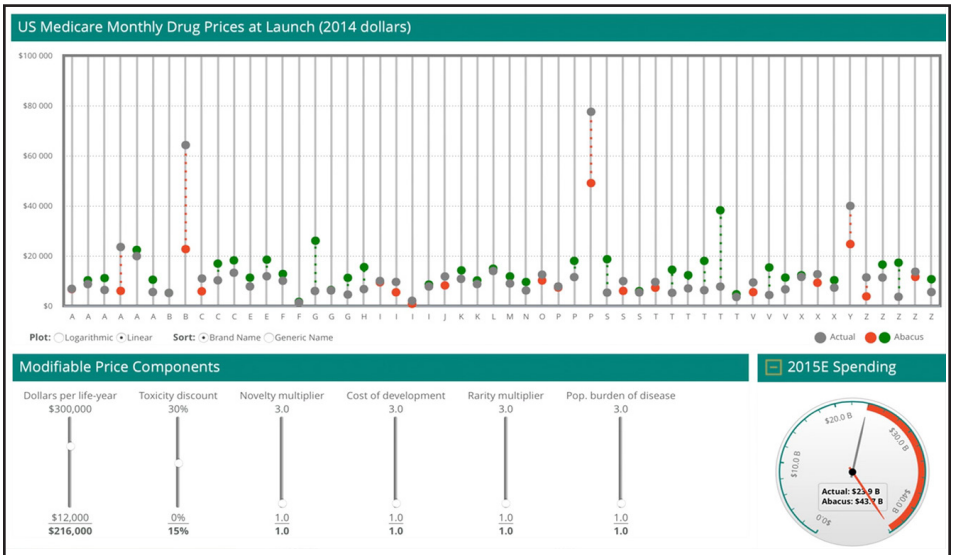

Are Cancer Drugs Worth the Money? MSKCC Tool Tests Pricing Rationale

A health services researcher at Memorial Sloan-Kettering Cancer Center has proposed a method for assessing whether cancer drugs are rationally priced.

Peter Bach, director of the MSKCC Center for Health Policy and Outcomes, constructed DrugAbacus, a tool for analyzing the value of the new generation of cancer drugs.

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Appropriations

House Spending Bill to Eliminate AHRQ While Adding $1.1 Billion to NIH Budget

By Nick Crispino and Matthew Ong

A $153 billion spending bill that cleared a House subcommittee June 17 seeks to abolish the Agency for Healthcare Research and Quality, the federal entity that funds patient-centered outcomes research and monitors the manner in which medicine is practiced in the U.S.

At the same time, the bill proposes increasing the NIH budget to $31.2 billion, a $1.1 billion above this year's level and $100 million more than the White House requested.

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AAUP Censures MD Anderson

By Matthew Ong

MD Anderson Cancer Center has been censured by the American Association of University Professors, an organization that defends academic freedom and shared governance.

The decision was made at AAUP's annual meeting, which concluded June 13 in Washington, D.C. Founded in 1915, AAUP has 47,000 individual members and 300 chapters.

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Bach's DrugAbacus Gauges Value of Cancer Drugs

(Continued from page 1)

"I created DrugAbacus because, as I thought about the concept of value and discussed it with many colleagues across the spectrum of the cancer world, I kept coming upon consistent themes, and in DrugAbacus I've made an attempt to operationalize each of them, while handing users the flexibility to determine how much each should contribute to value," Bach said to The Cancer Letter.

By making DrugAbacus publicly available, Bach is, in effect, challenging users to come to his website, click around and form their own conclusions.

The tool proposes the variable components that should be considered in price-setting and allows users to assess the value of 54 cancer drugs that have received U.S. approval since 2001—the year the targeted drug Gleevec hit the market.

"The current system is irrational. I had zero expectation that the DrugAbacus could be placed at any settings and explain current pricing," Bach said. "If it could, well, in a sense, we wouldn't need it, because that would tell us there was a coherent approach to pricing linked to quantifiable elements of value. We don't."

Bach's timing couldn't be better.

The word "value" is in vogue with everyone with a stake in oncology. Alas, people who use the v-word—the government, insurers, pharma companies, professional societies and patient advocates—often mean very different things.

"I think DrugAbacus is a fantastic attempt to illuminate a dark corner of the market for cancer drugs," said Clifford Hudis, chief of Breast Medicine Service at the Department of Medicine, vice president for government relations and chief advocacy officer at MSKCC. "What is a treatment worth is a complex question with deeply subjective answers. This may help many stakeholders begin to understand what drives their thinking and decisions."

"I applaud Dr. Peter Bach and his colleagues at Real Endpoints for the intellectual and financial investments they have made to move value-based pricing forward," said Michael Kolodziej, national medical director of Aetna Oncology Strategy.

"Their Abacus tool uses a variation of health technology assessment, the methodology currently used by agencies such as NICE in the U.K., to focus attention on the prices set by manufacturers at the time of FDA approval and market release. The goal is to more closely align value to the cost of these new agents, something the U.S. is reticent to do," Kolodziej said.

"The unique feature of the tool is the ability to "customize" the factors that enter into the value equation, so the user might place a relatively greater weight on efficacy, or toxicity, or another factor (such as "novelty of the biological mechanism"). The Abacus is a good start. Several practical issues may need to be addressed to increase the usefulness.

"The limitations include the difficulty in identifying clinically meaningful endpoints beyond survival, the reality of combination therapy in oncology including the cost of supportive care drugs, the challenge of expanded indications of agents over time, and the frequent change in measured impact as clinical data matures. Still, Dr. Bach is to be congratulated for bringing this discussion to the fore. It is overdue.

"Additionally, further discussion on how various stakeholders use the tool will be valuable. For example, clinicians might find it useful as part of shared decision making with patients, particularly those with substantial out of pocket expenses. Certainly, providers or vendors that develop and maintain content for clinical decision support tools ("pathways" programs) will applaud the ability to quantitate and support their recommendations," he said.

"At the same time, currently payers including CMS will be challenged to use the tool to craft coverage policy given the current standard of uniform coverage for all FDA (and also compendium) labelled indications. However, the tool could prove useful when drugs are therapeutically equivalent or in contracting."

Mark Ratain, the Leon O. Jacobson Professor of Medicine and associate director for clinical sciences at

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the University of Chicago Cancer Research Center, said drugs provide value in very different ways.

"This includes value to a population of patients who receive the drug under conditions with known clinical benefit, as well as value to society," Ratain said. "The former can be calculated; the latter is more challenging.

"Parts of what Bach has helps set the value for the patient receiving the drug," Ratain said. "But the value to the patient is not necessarily what the revenue should be to the company. In some cases—especially when a drug represents an innovation—money should come from other sources, such as the government."

Bach has been a long-time critic of drug pricing in the U.S. In 2012, he and two MSKCC colleagues challenged the price of the drug Zaltrap, saying that at introduction it was about twice as expensive as a similar drug, Avastin. This triggered an unprecedented price rollback.

Bach discussed DrugAbacus with Paul Goldberg, editor and publisher of The Cancer Letter.

Paul Goldberg: *Peter, thanks for giving me a preview of DrugAbacus. Clicking around, I see an effort to construct a rational system for drug pricing. Before you take me through this tool, can you tell me why it's necessary?*

Peter Bach: I think we've reached a point where it's clear the current pricing system is broken. Prices for cancer drugs at introduction have risen 100-fold since 1965, after adjusting for inflation.

The price of Gleevec is up nearly threefold since it was approved in 2001, even as competitors have entered the market and the company has vastly exceeded anyone's wildest dreams of profit from it. Our recent paper showed the cost of a year of life goes up $8,500 each year on average with rises in drug prices.

Even when you look to see if a novel drug gets a premium, the answer is no. Often their follow-on does instead. So prices don't make sense; neither can you find any evidence that drugs are priced on their value.

That last statement, of course, means we have to know what value actually is. Right now, it's more an abstraction, an eye-of-the-beholder concept. But I don't think it needs to remain that way.

I created DrugAbacus because, as I thought about the concept of value and discussed it with many colleagues across the spectrum of the cancer world, I kept coming upon consistent themes, and in DrugAbacus I've made an attempt to operationalize each of them, while handing users the flexibility to determine how much each should contribute to value.

The themes seem to fall into three buckets: patient-centric, innovation-centric, and society-centric.

• Patient-centric domains in DrugAbacus are health gains and side effects.

• Innovation-centric are the cost of developing the drug and how novel it is.

• Society-centric are the rarity of the disease targeted and the population health burden of it.

Some, maybe all, of these six domains might be considered when contemplating a cancer drug's value.

DrugAbacus lets users combine them based on data on 54 of the cancer drugs approved in the US since 2001, when Gleevec was approved. Using different weighting to these parameters, users can see what would happen to launch prices and spending under different value standards.

In other words, it's sort of an interactive *gedankenexperiment*, an attempt to move us from an abstract debate over whether we should have prices linked to value to how would we actually do that, given the various parties whose interests need to be contemplated.

PG: *Let's not start clicking yet. Please, try to take your hand off the mouse, if you are able. How does this project fit into the body of work you've created over the past five years or so?*

PB: I've been very concerned about the market for cancer drugs, that prices are rising unabated.

That regulations and laws ensure that will continue to happen. That incentives linked to the ability to profit from drugs has lead to distortions in treatment and healthcare markets, not just due to buy and bill, but also the impact of 340B on provider consolidation.

And coinsurance costs are rising. There was an abstract at ASCO that showed that currently around 10 percent of patient diagnosed with cancer in Medicare face out-of-pocket costs that exceed their income.

We know patients don't take their drugs for CML because of costs, too.

That's just intolerable.

We should be pursuing rationality in pricing, I'd like to see us get providers and hospitals out of the business of buying and reselling drugs to their patients' insurers at a profit, and I'd like to find a way forward where patients don't bear the brunt of our being unable to deal with pricing and benefit structure irrationality.

In the ideal, drug prices would match a value standard that was common, and when they did, doctors and hospitals would play no role in the transaction, and insurers would not pass on burdensome bankruptcy inducing co-payments.

PG: *Can you tell me what you are seeing—what's the one-sentence summary of what this project demonstrates?*

PB: We could do this. We could find a formula

for value that was transparent and applicable across cancer drugs.

PG: *Now let's look at the components of price. How did you determine what they should be? Now we can click around. Let's start with the societal assumption of acceptable cost per year of life. Where do we set the first parameter—acceptable price per added year of life?*

PB: I don't know. Honestly, I don't.

I can set it to about $110,000 per life year, and with everything else at zero I am about at current spending. But that means nothing.

The reason DrugAbacus allows you to change this setting and the others, and the allowed range is huge (from $12,000 to $300,000) is that we need to find your own number.

The U.K. uses about $50,000 per quality-adjusted life-year.

DrugAbacus does not have quality adjusted-data, so it will tend to make drugs look like a better value than they are, if you believe in quality adjustment.

PG: *In oncology, we don't often get to talk about adding a year of life. What's the value of delaying progression, which is what many new drugs do?*

PB: Let me unpack that. DrugAbacus uses survival data, unless all it has is PFS or TTP, in which case it considers the size of the gain to be the same as OS.

That's not an ideal assumption; sometimes PFS overestimate OS gains, sometimes it's the opposite.

Clearly, it is OS that is the patient-centered endpoint, but all we can go on is what is available, and I take seriously the problem of crossover after progression in many approval trials down biasing the estimates of OS benefit.

In other words, I don't think we can say definitively that because a drug was approved on RR or PFS or TTP that it doesn't improve survival.

PG: *Let's keep playing with DrugAbacus. Could you tell me how to set the rest of the parameters? What do we see?*

PB: I don't know how to set them, that's why the user can change them.

What I feel reasonably confident in is that this version of DrugAbacus already has a reasonable cross-section of the domains that might contribute to a coherent definition of value, and the data on the specific drugs is a reasonable, albeit somewhat incomplete, operationalization of each of those domains.

PG: *How many drugs have you plugged into DrugAbacus so far? How did you choose them? How many more are you going to add to this tool?*

PB: There are 54 drugs.

I started with the drugs approved in 2001 through 2013 that David Howard profiled in an econ journal (I was a co-author).

Then I added drugs approved since then. It's a representative sample, but we're missing about a dozen-plus drugs for various reasons, but no systematic ones. I sort of knew we couldn't do more than that for the first version.

In terms of what's next, I think separating drugs into their indications is important because value varies so much.

We have to factor in the costs of delivering the drugs, because sometimes that's a meaningful additional cost. Blincyto requires hospitalization, for instance.

PG: *How rational are the prices you see? Are there drugs that are outliers in either direction? By how much? What are the highlights?*

PB: This isn't about individual drugs' prices; it's about how we should pay for drugs.

The current system is irrational. I had zero expectation that the DrugAbacus could be placed at any settings and explain current pricing. If it could, well, in a sense, we wouldn't need it, because that would tell us there was a coherent approach to pricing linked to quantifiable elements of value. We don't.

PG: *What's your intended audience? Is DrugAbacus a policy-making tool, a price-setting tool, a tool intended to help patients make decisions, or a tool for shaming pharma companies into behaving differently?*

PB: All of the above, except for the shaming part.

Although you hear insurers, [pharmacy benefit managers] and employers complaining the loudest about drug pricing, the real crisis is actually in pharma's model.

It's the manufacturers themselves who are worried we don't have a logical way to pay for stacked therapies even though we have a sense and a few examples how this might be a big part of our future.

And they are the ones who realize that there are breakthroughs coming soon that might really shake up how we think about benefits in oncology because they could be large for treatments given over short durations. No model today accommodates that kind of value.

They also realize that the pay for performance model, which is a retroactive value payment system in which payments are adjusted over time based on how well a treatment works in an individual patient, will never easily reach across the majority of therapeutic areas and indications without huge added cost and administrative burden, and so an expected value pricing model makes more sense—i.e. one that starts to resemble the outputs of DrugAbacus.

PG: *Thanks so much for speaking about this with me.*

Appropriations

House Bill Would Eliminate AHRQ, Increase NIH Budget

(Continued from page 1)

The legislation—which passed the Appropriations Subcommittee on Labor, HHS, Education and Related Agencies—seeks to halt the implementation of the Affordable Care Act by rescinding previously allocated funds and prohibiting the use of any additional money to implement the law. A similar attempt was made in 2012 (The Cancer Letter, July 20, 2012).

The bill would move the independent U.S. Preventive Services Task Force to the Office of the HHS Assistant Secretary for Health, where, observers say, it may not be as shielded from political interference. The 1998 Public Health Service Act and the 2010 Patient Protection and Affordable Care Act instruct AHRQ to provide administrative, research, technical, and communication support to USPTSF.

"This bill includes provisions that ensure that not one dime of federal tax dollars provided to the Department of Health and Human Services can be spent and do any more work on the President's unpopular health care law," Subcommittee Chairman Tom Cole (R-Okla.) said during the subcommittee markup June 17.

The legislation would rescind $6.2 billion in mandatory funding for the Center for Medicare and Medicaid Innovation, which was created in the ACA.

The bill strikes out funding for the new Center for Consumer Information and Insurance Oversight and Navigators programs.

Overall, the 167-page bill—$3.7 billion below fiscal 2015 levels—falls $14.6 billion short of President Barack Obama's budget request.

Many cancer research institutions are involved in outcomes research.

The NIH budget goes up to $31.2 billion, $1.1 billion more than the 2015 level and $100 million more than Obama requested. NIH would receive increases for several targeted research initiatives, including:

• $200 million for the Precision Medicine Initiative—the full amount requested by the President;

• A $95 million increase for the Brain Research through Application of Innovative Neuro-technologies (BRAIN) initiative, for a total of $150 million;

• A $300 million increase for an Alzheimer's disease research initiative, for a total of $886 million;

• And a $100 million increase for an antibiotic resistance initiative, for a total of $461 million.

The proposed $1.1 billion increase for NIH is encouraging, but lawmakers need to iron out some issues in this spending bill to avoid gridlock, said Jon Retzlaff, managing director of science policy and government affairs at the American Association for Cancer Research.

"The House Labor, Health and Education bill that cleared the subcommittee on Wednesday underscores the need for Republicans and Democrats alike to work together to agree on some kind of broader budget deal to raise the sequester-imposed funding caps for FY 2016, especially when considering that the subcommittee has been tasked with passing a bill that is $6 billion below current (FY 2015) funding levels, including proposals to defund implementation of the Affordable Care Act, terminate the entire Agency for Healthcare Research and Quality, and eliminate 19 programs within the Education Department," Retzlaff said to The Cancer Letter.

"With Senate Democrats threatening to filibuster all spending bills that adhere to the sequester budget caps, and the President also determined to veto any of the spending bills that arrive at his desk adhering to the budget caps, there is a great opportunity now for everyone to come together to ensure that additional resources are provided for both defense and non-defense discretionary programs."

Defunding AHRQ is a strategic mistake, said Research!America CEO Mary Woolley.

"[It wipes] out research that informs the delivery of medical advances to patients," Woolley said in a statement. "Our nation can't afford to waste lives, time or dollars on preventable medical errors, lags between new discoveries and their application, and health interventions that fail to do what they are supposed to do.

"AHRQ-funded research provides the knowledge needed to dispense with what doesn't work and leverage what does."

Investigator Salary Caps, CDC, and Title X

The House bill proposes an 8 percent cut to the maximum salary level for investigators doing NIH-funded research.

"Awhile back it was an Executive Level I, and then it went to an Executive Level II and this proposal takes it to an Executive Level III," said Ann Bonham, chief scientific officer of the Association of American Medical Colleges. "What this means is the maximum salary that can be part of an NIH grant is about $182,000. This bill reduces the maximum salary by 8 percent.

"That's devastating, because it comes at a time when discretionary funds in academic medicine from the clinical revenue and other revenue is very tight and very fragile," Bonham said to The Cancer Letter. "Our

study shows that for every dollar of sponsored programs, our institutions are putting in an average of 53 cents for every dollar put in by mostly the government.

"Somebody has to cover that gap and that has fallen historically on academic medical centers and universities. Institutions are now going to be forced to say, 'How can we cover the salaries of these investigators, and do we have the resources to do it and take that one step forward? Well, we don't have the resources to do it.'

"This really has a huge effect at a time we're trying to advance patient-centered outcomes research, and we are saying we're not going to invest in physician-scientists' salary through NIH grants. The question is, 'Can institutions support it or are we going to leave the gap to investigators?'

"Even the most committed young physician-scientists might think twice about going into medical research. We're very concerned about that."

The Centers for Disease Control and Prevention would receive $7 billion, $140 million above the center's 2015 budget—with $6.1 billion in appropriated funds for the CDC, as well as $914.3 million in transfers from the Prevention and Public Health Fund.

The legislation increases funding for CDC's Public Health Preparedness and Response by $108 million over last year's level, providing a total of $1.56 billion to ensure that the Strategic National Stockpile and State and Local Preparedness capacity is adequate. These programs provide supplies and response efforts in the event of a bioterror attack or pandemic disease emergency.

Also, the bill would eliminate funding for Title X, a federal grant program that supports a network of family planning providers offering birth control, cancer screenings, STD testing, and reproductive health treatment to millions of low-income women across the country.

"We find ourselves with a bipartisan bill that would eliminate Title X family planning despite it being recognized by the CDC as one of the most significant public health achievements of the 20th century," Congresswoman Nita Lowey (D-N.Y.), ranking democrat on the House Appropriations Committee said during the subcommittee markup.

Lowey proposed a $300 million amendment which would reverse a decrease in funding for Title X, but it failed to pass.

The bill, as it currently is drafted, rolls back the clock at a time when women cannot make their own health care decisions, Rep. Rosa DeLauro (D-Conn.) said at the subcommittee markup.

"It's another example of an attempt to encode a divisive ideological preference into law, no matter what the cost, we need to stop pushing ideological agenda that places millions of women at risk," DeLauro said.

AAMC: Push to Eliminate AHRQ "Very Disquieting"

What's the genesis of the House proposal to eliminate outcomes research?

"I don't have an answer to that. There is some wonderment in the research community, 'Where did this come from?'" said AAMC's Bonham. "Lobbying against one agency that is integral to the sole spectrum of medical research is just extremely shortsighted."

Despite the proposed increases for NIH, eliminating AHRQ would jeopardize the translation of discoveries at NIH into medical practice, Bonham said.

"On the one hand, there's this 3.6 percent increase, the $1.1 billion in this draft for NIH is very much welcomed by the entire research community," Bonham said. "The bill focuses some of it on Alzheimer's disease, antimicrobial resistance, the BRAIN Initiative, the Precision Medicine Initiative. Those indicate strong support for fundamental discovery, and then there's this rub which essentially abolishes the office that can help translate those findings that come from the BRAIN initiative and Alzheimer's disease into improvement of health care delivery and screening.

"It's just hard to reconcile, and added to this, there seems to be no alternate resources to fund AHRQ. It is very disquieting, very disconcerting.

"Let's use cancer as an example. Through scientific research, we know the pathophysiological pathways, we know genomic underpinning of certain tumors and that comes from basic science and then if we take that one step further we have clinical trials to test targeted cancer treatments for some forms of cancer.

"Now there is a third step to that and that is the optimal use of proven cancer therapies in hospitals and by care providers, quality improvement around referral or procedure and access to health care and prevention and cancer screening. Those last steps are funded by AHRQ.

"Can we really continue to have an impact on the health of Americans without attention to the full scope of the medical research and around cancer?

"To me it's like building a super highway of fundamental discovery, and then have no regard for ramps, access lanes, local roads, or traffic. How would commuters, communities and travelers benefit from these fundamental discoveries or express lanes that never connect the patients and persons to where they live?

"Without AHRQ, we're missing that final portion. This is not a theoretical exercise, this has real consequences for building on the research that AHRQ compliments largely through the NIH."

AAUP Censures MD Anderson

(Continued from page 1)

Several hundred AAUP members voted unanimously to censure Ronald DePinho's administration, said Gregory Scholtz, AAUP associate secretary and director of the Department of Academic Freedom.

"There was no debate," Scholtz said to The Cancer Letter.

The censure concludes an acrimonious, yearlong feud between the two institutions, which began in April 2014. At that time, DePinho and his administration's refusal to provide justification for denying tenure renewals to Kapil Mehta and Zhengxin Wang triggered an AAUP investigation. MD Anderson's Promotion and Tenure Committee had unanimously recommended both professors for renewal (The Cancer Letter, April 25, 2014).

MD Anderson will now be listed on AAUP's censure list of over 50 institutions. There is no other top-tier cancer center on that list.

Three other institutions—University of Illinois at Urbana-Champaign, University of Southern Maine, and Felician College—were also censured at the annual meeting.

The decision to censure MD Anderson is based on the April 8 AAUP report, which found that DePinho's administration acted in disregard of academic standards and the cancer center's internal faculty appointment policy (The Cancer Letter, April 10).

"We believe MD Anderson's time-tested system of offering renewable seven-year appointments to our faculty members not only promotes academic freedom but also fosters exceptional individual achievement and maintains the institution's global impact on the cancer problem," said DePinho in a statement.

"In addition, years of data demonstrate our consistent pattern of renewing faculty appointments in almost all cases. Our world-renowned physicians and researchers remain committed to accomplishing our mission to end cancer, and together we will continue to forge ahead with our critical work for the benefit of cancer patients everywhere."

University of Texas System Chancellor Bill McRaven said: "As a specialized research-based cancer care institution with the singular mission of saving lives, MD Anderson's term appointment process has worked exceptionally well to ensure the recruitment and retention of world class, high impact faculty.

"Its successful process has been in existence for decades and has been instrumental in keeping MD Anderson at the forefront of the world's most formidable cancer centers. Moreover, MD Anderson's practice of renewable, multiple-year appointments is in compliance with The Rules and Regulations of the Board of Regents of The University of Texas System," McRaven said in a statement.

"Instances of non-renewal of faculty appointments are rare due to the high number of preeminent scientists and doctors who have been successfully recruited and retained to dedicate their lives to the MD Anderson mission."

Responding to the AAUP report at the time, MD Anderson officials characterized it as an effort on the part of a "labor union" to attract more members.

According to AAUP, the censure list is closely watched by about 240 higher education and academic organizations that endorse AAUP principles. Job postings and other related media from censured institutions published in that network would be accompanied by a footnote that reads, "The administration of this institution is on the AAUP censure list."

In advance of the organization's annual meeting, AAUP's Committee A convened May 29 to make a recommendation to censure DePinho's administration.

The full text of the committee's statement follows:

The report of the investigating committee focuses on the cases of two long-serving full- time faculty members who were involuntarily separated from service when the cancer center's president declined to renew their term appointments, despite unanimous recommendations favoring renewal from the faculty personnel committee and despite their evidently having met the requirements for reappointment.

Notwithstanding their many years of service, neither faculty member held an appointment with indefinite tenure. MD Anderson is one of two institutions in the fifteen-member University of Texas system exempt from the system's tenure policy. In its place, the cancer center awards renewable seven-year term appointments, referred to in the institution's policy documents as "term tenure."

Both professors were denied a timely written statement of the reason for the nonrenewal of their appointments, and only one of them was afforded the opportunity to appeal the decision to a faculty body. Although the institution's policies require that appeals of nonrenewal of term tenure be addressed exclusively to the president, an exception was made for one faculty member, who was permitted to file a preliminary appeal with a faculty committee. The appeals committee found in his favor, though an administrative officer concealed that information from the faculty member. His final appeal to the president was unsuccessful.

The other professor, in accordance with the

institution's policies, was not allowed to contest the decision through a faculty body. He declined to appeal to the president, concluding that it would be futile to expect a favorable review from the official who himself had made the nonreappointment decision.

During the period covered by the report, the administration had exerted increasing pressure on basic-science faculty members to obtain grants to cover larger portions of their salaries and on clinical faculty members to treat more patients, with what the faculty claimed were deleterious results for research and patient care. That period also saw an increasing frequency in presidential rejections of unanimous faculty personnel committee recommendations for appointment renewal, reducing the faculty's confidence in the fairness of the reappointment process.

As a consequence, faculty members could be inclined to select lines of research for their fundability and predictable results. And they tended to censor their own discourse, especially in the years immediately preceding renewal decision.

The investigating committee also inquired into the administration's removal of faculty status from a third faculty member because he lacked a Texas medical license. The professor's initial letter of appointment made no mention of any such requirement, his chair had regularly assured him that a temporary license would suffice, he was not provided promised time to study for the licensing exam, and other similarly situated faculty members were not required to obtain such a license, leaving open the question of the real basis for the decision.

The investigating committee found that the administration acted in disregard of the Association's Recommended Institutional Regulations on Academic Freedom and Tenure and of its own policies when it failed to furnish the two professors with written statements of the reasons for the decisions not to renew their appointments and when it failed to provide accurate licensure information to the third professor, leading to his loss of faculty status; of the Statement on Government of Colleges and Universities when it failed to provide compelling reasons stated in detail for rejecting the recommendations of the faculty personnel committee, when it unilaterally appointed department chairs, and when it failed to involve faculty in academic decisions; and of the 1940 Statement of Principles on Academic Freedom and Tenure, which calls for extending the procedural protections of tenure to full-time faculty members whose service exceeds seven years, when it failed to afford the two nonreappointed professors an adjudicative hearing before an elected faculty body in which the burden of demonstrating adequate cause for dismissal would rest with the administration.

Committee A recommends to the One Hundred and First Annual Meeting that the University of Texas MD Anderson Cancer Center be added to the Association's list of censured administrations.

Congress Reintroduces Bill To Limit Out-of-Pocket Costs For Oral Anticancer Drugs

By Nick Crispino

House and Senate sponsors have reintroduced the Cancer Treatment Parity Act, a bill that would require insurers to provide coverage for oral anticancer drugs on terms no less favorable than coverage for intravenous chemotherapy.

Previously introduced in 2011 and 2013, the 2015 version would reduce out-of-pocket costs for oral chemotherapy, but would not mandate coverage of oral medications.

The legislation, S. 1566 and H.R. 2739, has been referred to the Senate Committee on Health, Education, Labor and Pensions and the House Committee on Energy and Commerce.

The bills are spearheaded by Sens. Mark Kirk (R-Ill.), Al Franken (D-Minn.), and Reps. Leonard Lance (R-N.J.) and Brian Higgins (D-N.Y.).

The bipartisan legislation can improve access to cancer treatments, said American Cancer Society Cancer Action Network President Christopher Hansen.

"ACS CAN applauds this important, bipartisan legislation that has the potential to remove barriers to critical treatments by ensuring patients and their oncologists can continue to decide on a course of treatment based on what is best for the patient, not by what is covered by insurance," Hansen said in a statement. "Scientific advancements during the past several years have increased the availability and effectiveness of oral medications for cancer treatment, but health plans have often required higher cost-sharing for cancer treatments taken by mouth rather than administered intravenously by a doctor.

"This disparity can affect patient and physician decision-making about treatment options and may lead patients to forgo the best treatment for their situation. In addition, research suggests high cost-sharing for oral chemotherapy medications may lead patients to abandon treatment."

Oral chemotherapy is more convenient for patients who otherwise must travel to receive out-patient

treatment at a hospital or doctor's office, according to the American Society of Clinical Oncology.

"ASCO strongly supports the Cancer Drug Coverage Parity Act, bipartisan legislation recently introduced in both the U.S. House and Senate that would require private health insurance plans offering intravenous cancer drug benefits to provide parity for orally administered and self-injectable cancer drugs said in a statement," ASCO said in a statement.

Lower out-of-pocket costs for patients mean they are more likely to adhere to their anticancer regimen, ASCO said in a statement in 2013, when the bill was last introduced.

"Several studies have shown that the higher the cost-sharing amounts, the less likely patients are to follow through on their treatment," ASCO said. "Oral oncology drugs target specific biologic processes in cancer cells and block their growth—in contrast to conventional infusion agents, which often kill both cancer and healthy cells."

"For these reasons, oral and patient-administered chemotherapies are becoming the standard of care for many types of cancers," the American Society of Hematology said in a statement. "However, insurance coverage for these therapies is often different than IV drugs, leaving many patients responsible for unsustainably high monthly co-payments and forcing them to choose between their physical and financial health.

"These choices can have tragic consequences if the patient chooses based on financial considerations to forgo medications that can be curative.

"ASH supports anticancer drug parity legislation and will continue to work with Congress to identify supporters of this legislation in the House and in the Senate."

Advocacy for the measure started in 2008, when Oregon became the first state to implement a law requiring private insurers provide equal coverage for orally administrated anticancer medication.

To date, 39 states and the District of Columbia have enacted laws mandating coverage parity for oral and traditional chemotherapy.

Federal legislation is needed in addition to state legislation to ensure all insurance policies provide parity for oral treatments, according to the Association of Community Cancer Centers.

"Language of the laws varies across the states and only federal legislation will ensure the same protections for all patients," ACCC said in a statement. "State laws only impact state-regulated plans. Federal legislation is needed to cover self-insured plans.

CPRIT Reaches Milestone in Providing 2 Million Cancer Prevention Services to Texans

The Cancer Prevention and Research Institute of Texas has provided more than 2 million cancer prevention services to Texans across all 254 counties in the state, the institute announced June 16.

Prevention measures funded by CPRIT grants include tobacco cessation programs, vaccinations, screening for breast, cervical, and colorectal cancers, genetic testing and counseling, and survivor care.

Established in 2009, CPRIT has awarded more than $1.3 billion in grants to Texas researchers, institutions and organizations.

The 2 million milestone is a momentous occasion for CPRIT's history, said CPRIT CEO Wayne Roberts.

"Our innovative and proven cancer prevention strategies are saving or extending the lives of thousands of Texans who ordinarily might not have access to screenings and diagnostics," Roberts said. "The greatest opportunity to reduce the burden of cancer is by reducing its incidence—preventing it altogether."

CPRIT has delivered 2,211,119 prevention services to Texans—including 1,105,907 education and training services and more than 1.1 million clinical services—comprising of:

• 16,562 prevention vaccinations;

• 189,842 Texans receiving tobacco cessation services;

• 17,036 Texans receiving genetic testing and counseling, and

• 10,743 Texans receiving survivor care

"I get asked, 'When are we going to find a cure for cancer?'" Becky Garcia, CPRIT's chief prevention and communications officer, said in a statement. "My response is that we have a cure for cancer. It's prevention. For example, if people stopped smoking, an estimated 80 percent of lung cancer deaths could be prevented along with 30 percent of other tobacco related cancers."

In the Dallas area alone, the CPRIT-supported Bridge Breast Network has detected 226 cancers, including seventy-eight percent in the early stage. "That's 176 women who have a better chance at survival now," Garcia said. "It makes a huge difference detecting breast cancer early when treatment is most effective."

To date, CPRIT has funded 146 cancer prevention grants totaling $142,189,920. Of the 1,105,212 clinical preventive services delivered, there have been

528,645 screenings and diagnostics for breast, cervical, colorectal, and liver cancers. Of these: 42,991 abnormal results were identified, 3,340 cancer precursors were detected, and 1,477 cancers were found.

Up to 10 percent of the total amount of money CPRIT awards each year is specifically devoted to delivering cancer prevention programs and services in Texas.

Currently, CPRIT supports 55 prevention projects throughout the state. A full list of CPRIT's currently funded grants is available on its website.

In Brief

Sampson Named Chair of Duke Department of Neurosurgery

JOHN SAMPSON was named chair of the new Department of Neurosurgery within the **Duke University School of Medicine**.

In February, the Duke Board of Trustees approved the creation of a Department of Neurosurgery within the school. The current Division of Neurosurgery, within the school's Department of Surgery, will be elevated to department status, effective July 1.

Sampson has served as chief of the Division of Neurosurgery since February 2014. He is the Robert H. and Gloria Wilkins Distinguished Professor of Surgery, and he joined the division in 1998 after completing his training at Duke. His research has focused on drug delivery to the brain and immunotherapy for brain tumors.

He also has received a PhD in Neuropathology at the Duke Graduate School and an MBA at the Duke Fuqua School of Business.

JOHN ZAIA was named director of the Center for Gene Therapy within **City of Hope's** Hematologic Malignancies and Stem Cell Transplantation Institute.

Zaia, the Aaron D. and Edith Miller Chair in Gene Therapy, and past chair of the Department of Virology, is also the principal investigator of the new Alpha Clinic for Cell Therapy and Innovation at City of Hope.

He has served as chair of the Department of Virology since 1999, having joined City of Hope in 1980 as director of Virology and Infectious Diseases within the Department of Pediatrics. Prior to that, he was an instructor in medicine at Harvard Medical School and a clinical associate at Dana Farmer Cancer Institute in Boston.

A specialist in gene transfer as HIV-related therapy, Zaia has focused on two potential avenues for fighting AIDS. One involves genetic modification of blood stem cells as a way to create resistance to the virus that causes AIDS; the other involves genetic modification of stem cell genes so that they prevent replication of the virus.

THE AGENCY FOR HEALTHCARE RESEARCH AND QUALITY plans to fund three centers of excellence to study how high-performing health care systems promote evidence-based practices in delivering care. The grants were announced at AcademyHealth's Annual Research Meeting in Minneapolis by Richard Kronick, director of AHRQ.

According to the agency, the centers will identify the characteristics of health systems that successfully disseminate and apply evidence from patient-centered outcomes research, and they will analyze the connections between successful dissemination of patient-centered outcomes research, patient health outcomes and effective use of resources.

The grants, which will begin in September, will provide approximately $52 million over five years to study how complex delivery systems disseminate evidence-based findings and provide lessons learned to inform the dissemination of findings in other settings. This project is funded by the Patient-Centered Outcomes Research Trust Fund, which was created by the Affordable Care Act.

The three centers, their principal investigators, and their areas of focus include:

Dartmouth College, with principal investigator Elliott Fisher, in collaboration with the University of California at Berkeley, University and the High Value Healthcare Collaborative: Using mixed methods involving existing and ongoing claims-based data, the center will conduct a national survey of health care organizations and systems to understand the inner workings of systems, and in particular, how market and organizational factors influence the implementation of biomedical, delivery system and patient engagement innovations.

National Bureau of Economic Research, with principal investigator David Cutler, of Harvard University and the bureau, in collaboration with the Health Research & Educational Trust and the Network of Regional Healthcare Initiatives: This center will create a large national database to identify health systems in the U.S. and their characteristics and outcomes, as well as the evolving consolidation and integration of systems over time, and to use those data to study health systems nationally, with a focus on cancer care, pediatric health care delivery, dialysis and post-acute care.

RAND Corporation, with principal investigator Cheryl Damberg, in collaboration with Pennsylvania State University: This center will examine health systems in five regions with the goal of understanding the role of incentives, use of health IT and organizational integration within systems and its impact on performance and evidence dissemination.

ELI LILLY AND COMPANY announced two research collaborations.

The first, with **Dana-Farber Cancer Institute**, is a three-year collaboration to research new medicines, where Dana-Farber will provide research and development expertise for a number of early-stage Lilly oncology compounds.

Dana-Farber researchers and Lilly scientists will work on preclinical and clinical studies, molecular studies of patient samples and the design and conduct of clinical trials. The agreement also allows Dana-Farber scientists to conduct independent studies on select Lilly compounds. Following research conducted at Dana-Farber, the evaluated compounds will still be fully owned by Lilly. Financial terms of the agreement are not being disclosed.

The second, with **Sarah Cannon Research Institute**, is a partnership to co-develop an investigational oncology compound, LY3023414, a PI3K/mTOR dual inhibitor.

Under the agreement, SCRI will collaborate with Lilly to provide clinical development expertise and program design, as well as medical oversight and trial management. Patient enrollment for the initial phase II clinical trial is underway.

Drugs and Targets

European Commission Grants Authorization to Gardasil 9

The European Commission has granted marketing authorization for Gardasil 9.

Gardasil 9 is a nine-valent HPV vaccine for active immunization of females and males from the age of 9 years against premalignant lesions and cancers affecting the cervix, vulva, vagina or anus and also against genital warts (Condyloma acuminata) caused by the HPV types covered by the vaccine.

The approval of Gardasil 9 follows a positive opinion from the European Committee for Medicinal Products for Human Use, granted March 27. Gardasil 9 is sponsored by Sanofi Pasteur MSD.

"This vaccine is a significant step forward for public health; by vaccinating boys and girls we can prevent not only 90 percent of cervical cancers but also implement effective immunization programs to address other types of HPV related diseases such as anal, vulvar and vaginal cancers for which there is no current systematic screening," said Jean-Paul Kress, president of Sanofi Pasteur MSD.

Gardasil 9 includes more HPV types than any currently available HPV vaccine. The seven high-risk HPV types in Gardasil 9 (HPV 16, 18, 31, 33, 45, 52 and 58) cause approximately 90 percent of cervical cancer, 90 percent of HPV related anal cancer and 80 percent of high-grade cervical lesions (cervical precancers defined as CIN 2, CIN 3 and AIS) worldwide. The two low-risk types, HPV 6 and 11, cause 90 percent of genital wart cases.

The authorization is supported by a clinical program initiated in 2007; seven trials evaluated more than 15,000 individuals across 30 countries. Gardasil 9 was shown to be 97 percent effective in preventing high-grade lesions of the cervix, vagina and vulva caused by the 5 additional oncogenic HPV types (31, 33, 45, 52, 58). In addition, the vaccine was shown to elicit antibody responses against HPV types 6, 11, 16 and 18 that were non-inferior to Gardasil, the leading HPV vaccine.

Gardasil 9 will be commercialized in Western European countries by Sanofi Pasteur MSD (a joint venture between MSD and Sanofi Pasteur), in the United States and Canada by Merck, and in other countries (including Eastern Europe) by MSD.

FDA approved the Ventana ALK (D5F3) CDx Assay as a companion diagnostic to aid in the identification of patients for Pfizer's targeted therapy, Xalkori (crizotinib).

The assay was approved as a CE-IVD in Europe in 2012 and was approved by the Chinese Food and Drug Administration in 2013.

With this approval, ALK IHC testing is now accessible on the BenchMark immunohistochemistry instruments developed by Ventana Medical Systems Inc., a member of the Roche Group, and offers test results with a binary scoring method.

Xalkori (crizotinib) is an oral first-in-class ALK inhibitor that has been shown to block important growth and survival pathways which may shrink or slow the growth of tumors. It is indicated for the treatment of patients with metastatic non-small cell lung cancer whose tumors are ALK-positive