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NCI Frederick Laboratory's $400 Million Per Year Contract Up for Re-Competition

By Matthew Bin Han Ong

NCI is opening up its contract for operations and technical support at the Frederick National Laboratory for Cancer Research for re-competition—a process that officials said will take up to two years.

The institute is broadening the statement of work for the contract to maximize new opportunities in cancer research, which involves fostering interactions with academia. Bidders can include universities, consortia of universities, other nonprofit institutions and for-profit companies.

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21st Century Cures Heads for House Floor Vote

By Nick Crispino

The 21st Century Cures Act cleared the House Committee on Energy & Commerce and is heading for floor vote.

The legislation, H.R. 6, is designed to expedite drug development, modernize clinical trials, and accelerate approval of drugs and medical devices. Capitol Hill insiders say the floor vote may occur within two weeks.

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Guest Commentary

Obamacare was Undermined from the Outset

By Leonard Zwelling

Could the Supreme Court functionally end Obamacare before the end of June?

It could if the court determines that subsidies paid to those individuals eligible for the payments who gained health insurance on the federal exchanges are inconsistent with the Affordable Care Act as written.

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NCI Opens Frederick Lab Contract for Re-Competition

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The contract, which was awarded in 2008, is scheduled to end in September 2018. Leidos Biomedical Research Inc. received $400.2 million to run the lab in fiscal 2014. It is not publicly known how much NCI is budgeting for the 2018 contract.

The lab, located on the 68-acre campus in Frederick, Md., is one of 41 Federally Funded Research and Development Centers. FFRDCs receive 70 percent or more of their financial support from the federal government.

The Frederick lab is operated by Leidos Biomedical Research—formerly known as SAIC-Frederick—the same contractor that has run the lab since 1995.

The Frederick campus, which includes the Advanced Technology Research Facility, a 330,000-square-foot complex with a biopharmaceutical development wing, is the only federally funded research center dedicated to biomedical research, specifically in the areas of cancer and other diseases.

NCI officials said the re-competition announcement, which was published on the Federal Business Opportunities website May 27, is being initiated on schedule.

"Given the size and complexity of this award, we want to ensure that we have sufficient time to design and compete a contract that will support the changing needs of the cancer research community," NCI Acting Director Doug Lowy said to The Cancer Letter.

Does the next candidate for running the Frederick lab have to be a for-profit government contractor similar to Leidos?

"We do not have a predefined model in mind," Lowy said. "We are taking this opportunity to examine the FNLCR, what it does, and how it might be enhanced, and these considerations will be reflected in the solicitation for proposals.

"Competing a contract of this size and scope requires a significant amount of time to execute from start to finish, but we are committed to a thoughtful approach to enhance the contract's structure and leave an appropriate timeframe for a robust competition."

Leidos will be participating in the re-competition, said David Heimbrook, laboratory director of the Frederick facility, and president of Leidos Biomedical Research.

"Our current contract has a period of performance running to 2018, so we expected that preparations for a re-competition would begin soon," Heimbrook said to The Cancer Letter.

Using a contractor to operate the national laboratory gives NCI the flexibility to fund programs and hire staff without having to use government mechanisms—giving the institute the ability to shift projects and move dollars with greater ease.

In the past, NCI directors have sheltered their pet projects from peer review by funding them as subcontracts of the SAIC contract. Under previous directors, the institute has been known to use the contract as a depository for funds left over from the fiscal year, which can be reinvested in the following year's budget, sources said.

The Frederick National Lab evolved from a little-understood outpost of the NCI into a national laboratory in February 2012, two years after Harold Varmus was appointed NCI director.

On Varmus's watch, the Frederick National Laboratory Advisory Committee was created to guide its programs and "reuse resources in a sort of very sensible way to foster the best use of NCI's money." (The Cancer Letter, Feb. 28, 2014).

Varmus was succeeded by Lowy on April 1 (The Cancer Letter, April 17).

It's difficult to know whether specific agendas will change at Frederick until the re-competition process actually happens, said Joe Gray, chair of the NCI Frederick National Laboratory Advisory Committee, and Gordon Moore Endowed Chair, Department of Biomedical Engineering at Oregon Health & Science University School of Medicine.

"From my past experience, in a different setting,

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what came out of it was increased administrative efficiency and a better appreciation for what the role of the laboratory was on the part of the leadership of the laboratory," Gray said to The Cancer Letter. "I think that it caused the sponsor, in this case, NCI, to be able to take a critical look at what it expects from the Frederick Laboratory. The competition process is not just Leidos. It's a competition, and this is an opportunity to get several different views on what a national laboratory for cancer research might do for the country. I think that's a good thing."

Gray was a member of the leadership team that oversaw a similar process at the Lawrence Berkeley National Laboratory, when the University of California was asked to re-compete the laboratory for the Department of Energy.

"While that was a great deal of work, it was also a very beneficial process, because it actually forced us to sit down and think about the whole operation," said Gray, associate director for translational research at the OHSU Knight Cancer Institute. "Out of that came a much sharper focus for where the laboratory was going scientifically, and also for the administrative process.

"I think that it is important from time to time to step back and critically reevaluate how things are being done, and the re-competition process is a really good one," Gray said. "In the long run, the Frederick National Laboratory is going to be very well served by the re-competition process."

Contract re-competitions are routine for Leidos Biomedical Research's parent company, Leidos, Heimbrook said.

"We have been operating this FFRDC on behalf of the NCI for about two decades, so there have been many landmark accomplishments over the years. Working closely with the NCI, some of our most recent achievements include:

"We established a novel program targeting RAS-driven cancers, which are generally very difficult to treat. This program has been in place for only a couple of years, yet it has already generated new approaches on how to target the RAS oncogene and many new collaborations with academic and industry-based scientists.

"The Nanotechnology Characterization Laboratory has established itself as an essential national resource in helping move new nanomedicines for patients afflicted with cancer into clinical trials. Our scientists conduct basic and applied research to understand how to more effectively treat patients afflicted with AIDS, and the fundamental workings of the immune system. They collaborate with some of the best laboratories in the world and publish their work in leading biomedical journals.

"We are proud to support NIAID's urgent efforts in the nation's response to the recent Ebola crisis, by helping to manufacture Ebola vaccine candidates for clinical trials, and helping set up the capability to actually run those trials where they were most needed, in West Africa."

Universities May Apply

NCI officials said the re-competition process would prioritize entities with an established record of managing a complex research agenda.

"We are seeking proposals from organizations with a proven history of pursuing academic research, an ability to find and engage collaborators in a productive research environment, and experience managing a national resource, such as a FFRDC," Lowy said. "As we have discussed at a number of NCI advisory board meetings, we are broadening the statement of work for this contract to allow us to take greater advantage of new opportunities in cancer research.

"We believe the FNLCR provides the potential for dynamic collaborations with all entities, including academia, and we are designing this re-competition to encourage those collaborations.

"We look forward to receiving responses from any qualified entity that is capable of operating, managing, and administering a contract of this type and size, including universities; a consortium of universities; other nonprofit organizations; industrial firms identified as autonomous organizations (i.e., identified separately from any parent organization); collaborative industry/academic partnerships, such as an LLC; or some other legal arrangement formed for the purpose of operating a FFRDC.

"In terms of the next FFRDC contract, the contract will reflect a statement of work that addresses the changing needs of the cancer research enterprise and NCI's interest in fostering collaborations and partnerships to advance the field. As the path of research changes and as research develops and unfolds, the FNLCR's direction will follow."

NCI officials said they envision a "special, long-term relationship" with the contractor—similar to the one with Leidos. The specific details, such as period of performance, are being finalized with the Department of Health and Human Services.

"NCI will follow a formal source selection process in accordance with Federal Acquisition Regulation

(FAR) Part 15 and peer review conducted in accordance with 42 CFR Part 52h," Lynn Austin, NCI deputy director of management and executive officer, said. "This process includes the issuance of a request for proposals, responses to inquiries by potential applicants, the receipt of proposals, technical and business evaluations against established evaluation criteria through a peer-review process, negotiations with offerors, and the selection of an awardee."

The NCI Frederick National Laboratory Advisory Committee will be involved in examining how the lab is being run, Gray said.

"As chair of the advisory board, I think that it is important to ask the question, 'What is the most efficient way forward?'" Gray said. "We are in the process of trying to really take a critical look on what the best use of the Frederick National Laboratory is for the nation, in terms of its cancer research mission, and I think that the re-competition process will give us some guidance in terms of how to best do that.

"I think we would probably be in the position of evaluating the results of the competition, but I don't think it's our business to decide on the winner and so on. It is an opportunity for us to take a look at the ideas that come out of the re-competition process, and to help NCI make decisions on how best to proceed."

More information concerning the competitive process for the contract will be announced on Federal Business Opportunities (FedBizOpps) at www.fbo.gov, as well as at the FNLCR Acquisition Portal. According to NCI, information posted on FedBizOpps takes precedence over information provided elsewhere.

Also, the NCI Office of Acquisitions will host a pre-proposal conference designed to showcase the FNLCR and the innovative work currently being conducted there.

This will be a two-day event, scheduled for Oct. 1-2. The event will begin on Thursday, Oct. 1 at the NIH Natcher Conference Center, in Bethesda, Md., and will consist primarily of presentations and information concerning the FNLCR's mission and purpose, an overview of its scientific programs, and an overview of its management, facilities, and business operations. In addition, an overview of the draft Request for Proposals and submission instructions is planned. On Oct. 2, NCI will conduct guided tours of the FNLCR facilities in Frederick.

To register to attend this pre-proposal conference or to obtain further details, information will be posted on the FNLCR Acquisition Portal under "Events" as updates become available.

21st Century Cures Initiative Heads for House Floor Vote

(Continued from page 1)

Energy and Commerce passed the bill May 21 unanimously, by a 51 to 0 vote. The bill would allocate $10 billion in mandatory funding in new funds to NIH over five years. Another $550 million would go to FDA over the same period.

If the 309-page bill is enacted, funds could start to flow in fiscal 2016.

A parallel measure, called Innovation for Healthier Americans, is moving through the Senate Health, Education, Labor and Pensions Committee.

"Key provisions of this legislation pave the way for critically ill patients to have access to better drugs and treatments," Rep. Fred Upton (R-Mich.), chair of the committee, said in a statement May 21. "This historic day marks a big bipartisan step forward on our path to cures."

The legislation is spearheaded by Upton, Oversight and Investigations Subcommittee Ranking Member Diana DeGette (D-Colo.), full committee Ranking Member Frank Pallone Jr. (D-N.J.), Health Subcommittee Chairman Joe Pitts (R-Penn.), and Health Subcommittee Ranking Member Gene Green (D-Texas).

"ASCO applauds the bipartisan efforts that led to the completion of this legislative package, especially the inclusion of funding for the NIH and FDA," the American Society of Clinical Oncology said in a statement May 22.

Provisions in the bill of interest to clinical cancer researchers overall and ASCO in particular include:

• Standards for the use of single Institutional Review Boards of record for conducting multi-site research initiatives,

• Transparency requirements for expanded access programs,

• Standardized language and data, including eligibility criteria, for clinicaltrials.gov,

• Standards for FDA regulation of health information technology that account for risk while not stifling innovation, and

• Inclusion of patient experience data to enhance risk-benefit assessment in the FDA drug approval process.

"ASCO also thanks the committee for their efforts to address the interoperability of Electronic Health Records in a meaningful way," ASCO said in a statement. "However, we are still carefully analyzing whether this portion of the legislation will have a

negative impact on physician practices."

On May 13, 180 organizations—academic research institutions, scientific and professional societies—signed a letter in support of the NIH Innovation Fund, which was included in the updated discussion draft published the same day.

"The AACR is extremely pleased that members of the House Energy and Commerce Committee have been so committed to providing robust funding increases for the NIH and FDA in their 21st Century Cures legislation," said Jon Retzlaff, managing director of science policy and government affairs at the American Association for Cancer Research. "In fact, during the year-long process of developing the legislation, Congressional leaders, most notably Fred Upton and Diana DeGette, increasingly embraced the message that strong, predictable, and sustainable budget increases are vital for the NIH and FDA, especially since scientists today have such an abundance of research opportunities to pursue, many of which will benefit the millions of individuals living with cancer and their loved ones.

"The AACR is most grateful for this support," Retzlaff said to The Cancer Letter.

According to its sponsors, the bill encourages transparency, sustainability, patient safety, affordability, and encouragement in competition to find breakthroughs where no treatments are accessible.

"This effort covers the full cycle of discovery, development, and new treatments of cures," DeGette said before the committee vote. "We've harmonized the various rules surrounding IRBs and support a centralized system, we also support the use of more adaptive clinical designs and Bayesian statistics and we created a national neurological disease system to develop better data."

Critics say that this additional funding for NIH and FDA will come at the expense of other federal entities.

America's Health Insurance Plans, a lobbying group for the insurance industry, released a statement opposing the bill.

"Taking funds from the component of Medicare that is driving innovation for beneficiaries would contradict our shared goal of improving patient care and health outcomes for individuals with serious medical conditions," said America's Health Insurance Plans President Karen Ignagni in a letter to the House committee.

Other amendments in the bill include a provision that promotes the use of digital imaging by limiting Medicare's reimbursement for film X-rays as well as change the timetable of reinsurance payments to prescription drug plan sponsors under Medicare Part D.

This amendment was crafted to reduce the interest that can accumulate the longer it takes for reimbursement to be sent.

The bill no longer includes restrictions on the 340B Drug Pricing Program, which enables hospitals to purchase discounted drugs from pharmaceutical firms to supply them for low-income outpatients.

340Health, an organization representing more than 1,000 public and private nonprofit hospitals and health systems throughout the U.S. that participate in the 340B program, led protests against the restrictions.

Before the committee vote, more than 500 CEOs of hospitals and health systems signed a letter to Congress:

"If the program were to be restricted, vital services to the underserved would be cut back. Prescription drug costs for our patients would rise dramatically and taxpayers would have to pick up the tab."

Pharmaceutical Research and Manufacturers of America said the bill appropriately exempts the FDA user fees from sequestration. "Exempting future Food and Drug Administration user fees from sequestration is critical to ensuring the FDA is able to fulfill its public health mission by fostering timely patient access to safe and effective new medicines and advancing regulatory science," said John Castellani, the organization's president and CEO.

Several organizations said the expedited drug and medical equipment approval processes can lead to faulty products that erode public health and endanger public safety.

"Rather than addressing the true scientific bottleneck in drug and device development, the bill includes unnecessary, costly, and potentially harmful regulatory changes and financial incentives for pharmaceutical and medical device companies that would put patient safety at risk and undermine public health," said Public Citizen, a Washington, D.C. non-profit group, in a letter to the House of Representatives.

The letter was co-signed by National Physicians Alliance, American Medical Student Association, Treatment Action Group, Consumers Union, AIDS United, Knowledge Ecology, and International Young Professionals Chronic Disease Network.

Several lawmakers said more work is needed to responsibly offset the budgetary provisions in the bill.

"There's still work to be done on this legislation including identifying pay-fors," said Rep. Jan Schakowsky (D-Ill.) during a House hearing May 19. "We simply cannot pay for this legislation by further reducing benefits from Medicare or Medicaid beneficiaries or asking providers to accept further reductions in payments."

Guest Commentary

Five Ways Obamacare was Undermined from the Start

(Continued from page 1)

That is the essence of the King v. Burwell case that was argued before the Supreme Court on March 4 (http://healthaffairs.org/blog/2015/03/05/king-v-burwell-unpacking-the-supreme-court-oral-arguments/). A decision is expected any day.

I was present at the inception of the Affordable Care Act when the first U.S. Senate Committee considered, "marked-up" (discussed and amended), and voted (13 to 10 down party lines) the bill to the Senate floor in July of 2009. It was the first time that a health reform bill had actually made it into and out of a Senate Committee in over 50 years. Eventually it was passed through both houses of Congress and went to the president's desk where it was signed into law in March of 2010. That bill is Obamacare. I was there because I was on the staff of the Committee on Health, Education, Labor and Pensions as part of my Robert Wood Johnson Foundation health policy fellowship.

There were five major steps that define why this law is so flawed and actually undermines the President's goal of reforming health care delivery in America.

1. Poorly defining health care reform. The first undermining step is that most people define health care reform as increasing access of more people to health care, lowering health care costs, and improving its quality. This bill never dealt with cost or quality other than through demonstration projects and suggestions of payment reform. So those opposed to health care reform had already won the battle when cost reduction and quality improvement were not really in the legislation. And as far as access to health care is concerned, access to insurance is not access to health care so whether even what was passed has a significant effect on our nation's health remains to be seen.

2. A poor selection of how to pay for health insurance expansion. To increase access to health insurance for more of the 50 million Americans who were without it in 2009 would usually be done with a tax. Medicare is paid for with a federal tax and Medicaid is partially supported with federal tax dollars and state tax dollars. A similar tax system could be used to purchase private insurance for those who did not have it in 2009. Obamacare is not really such a system. Instead a system of mandates to buy insurance, computerized market places to shop for it, and subsidies for those who could not pay the premiums was the route taken to finance this system of health insurance.

There was also an expansion of Medicaid proposed to include all Americans under 138 percent of the federal poverty line (about $33,000 for a family of four). Most of this expansion was to be paid for with federal dollars until 2017. After that, 90 percent was still federally supported. Nonetheless, many states, particularly red states (Republican), did not want to incur additional revenue responsibilities to pay for Medicaid expansion. In the original law, if a state chose not to expand its Medicaid recipients, it would lose all the federal support it currently had to defray the cost of insuring its poorest and most disabled citizens. The choice of the method to fund insurance expansion (increased access) was not really a tax, so what was it? The Supreme Court would get to decide if this system of financing was constitutional.

3. Partisan politics and the subjugation of "regular order." The so-called "most important piece of social legislation passed in 50" years became law without a single Republican vote. This is because so-called "regular order" was not followed in its passage. The process of "regular order" in which legislation must be thoroughly reviewed and discussed in permanent committees of jurisdiction in both houses of Congress, and *ad hoc* conference committees especially established to resolve differences between Senate- and House-passed versions of bills, was completely upended by Speaker Pelosi and her allies. They knew that the loss of the 60 votes in the Senate when Scott Brown (R-Mass.) was elected to replace the late Sen. Ted Kennedy (D-Mass.) guaranteed a Republican filibuster of the Affordable Care Act. The only way to gain the bill's passage was to make sure there was no conference committee as is dictated by "regular order." Mrs. Pelosi by-passed "regular order" by passing the Senate version of the bill through the House. Not only was Senator Kennedy gone, but the ally Kennedy could have had at the Department of Health and Human Services, former majority leader Tom Daschle, had to withdraw his name from consideration for that post as he had failed to pay a great deal of federal taxes. So along with a the ACA being a bill that only partially addressed true reform and was financed by a Rube Goldberg-like scheme instead of straight taxation, the rules to getting it passed were not followed.

4. The Supreme Court makes Medicaid expansion optional. The Supreme Court weighed in on the ACA's constitutionality. In June of 2012 the court allowed the law to stand, BUT ruled that mandating Medicaid expansion was overly punitive and each state

could decide whether or not to expand the program without losing the federal support each already had. The current estimate is that 30 states have expanded Medicaid (http://familiesusa.org/product/50-state-look-medicaid-expansion) including California where over 2 million people have been estimated to have gained coverage as opposed to Texas where over 1 million might gain insurance if Medicaid would expand in the Lone Star State which it has not. Thus, the Supreme Court significantly undermined the remaining benefit to many Americans of Obamacare when Medicaid expansion became optional on a state-by-state basis. And the court could finish the job of undermining Obamacare soon.

5. King v. Burwell: Are all insurance premium subsidies equal?

The final nail in Obamacare could be a Supreme Court ruling for the plaintiff in King v. Burwell (http://www.scotusblog.com/case-files/cases/king-v-burwell/) later this month. The subsidies received by those insured using the federal insurance exchange (healthcare.gov) under the Affordable Care Act are being constitutionally challenged because the law says that subsidies go to those acquiring insurance in exchanges "established by the states." The federal exchanges are not established by a state. (Remember the law was written with the idea that the penalties to not establishing an exchange in a state would be too high—the loss of the federal portion of Medicaid. The Supreme Court removed this mandate three years ago creating a hodgepodge system of health insurance for the most needy.)

It really is unclear what the Supreme Court will do in this regard. Most court watchers expect Burwell to prevail along with the subsidies enjoyed by those insured under the ACA in states that have not established their own exchanges, but use the federal one. The ACA will probably not go away after the end of June 2015.

Why Obamacare Misses the Mark of True Health Care Reform

So we got this, the ACA or Obamacare. Does it really reform health care?

Health care reform is usually thought of as having those three parts—cost control; quality improvement; and enhanced access to care. In fact, Obamacare directly affects none of these. There are no mandated limits to spending on health care and it continues to rise driven by the aging population, the advancements in expensive technology (MRIs, CT scans, genetic testing), and the costs of everything from stents to novel anticancer drugs.

Quality is covered in many proposed Obamacare pilot and demonstration projects and some adaptations of payment systems but what is quality health care anyway?

Quality, too, has three parts. There's the part that is usually measured in patient satisfaction surveys that apply to patients' perception of the care they have received. This could depend upon the color of their doctor's tie or eyes, the duration of the wait to see him or her, whether or not the latest People magazine is in the waiting room, the presence or absence of a nearby Starbucks, or the availability of free parking. In other words, patient satisfaction may have little or any correlation with the true quality of the delivered health care.

Then what does?

A favorite of late is the checklist. The frequency with which a patient's arm band is checked as a nurse enters his or her hospital room, the number of times a doctor washes his hands, or the number of clicks on the electronic medical record it takes to actually find out why a patient came to see her physician are all part of the checklist mentality that so dominates modern medicine. Checklists are vehicles to quality. They are not quality.

What is quality? Most people consider clinical outcomes a good measure of quality and we in cancer medicine certainly do. It's one of the primary metrics of the goodness of any newly proposed treatment for malignancy—whether surgical, radiotherapeutic or systemic. Are responses better? Is quality of life improved? And the gold standard—is the quantity of life improved? Obamacare touches none of this.

Well, surely then at least it increases the number of people with access to health care, right? Not really.

Of the approximately 50 million Americans who did not have health insurance when this entire process began in early 2009, about 11 million or so now have insurance since the exchanges went live (2014; http://obamacarefacts.com/sign-ups/obamacare-enrollment-numbers/). This does not account for what percentage of these people had had other insurance before Obamacare became an option, but either way that is a clear improvement. Unfortunately, it still leaves over half of those needing insurance without it, many of those without it are the poorest Americans for whom Obamacare is still out of reach and for whom Medicaid expansion was blocked by the Supreme Court ruling in 2012 that made expansion of this insurance for the poor and disabled optional on a state-by-state basis. Many states chose not to expand Medicaid eligibility, so their most needy still are without insurance.

But the bigger access issue is that access to insurance is not access to health care.

• Do the newly insured have doctors?

• Do they still get their care in emergency rooms as many did before the advent of Obamacare?

• What programs have been implemented to educate the newly insured as to their options for health care?

• Are there sufficient numbers of providers of any kind to fulfill the needs of these newly insured?

• And, for our community, are there enough oncologists to handle the cancer diagnoses of these newly insured and is there any more clarity about what is meaningful cost-free cancer screening for these newly insured? It's fine if the preventative colonoscopy is paid for, but what happens to someone on a bronze plan if a cancer is found? That calls for treatment not prevention and the co-pay issue arises.

The real problem with Obamacare is that it really strove for so little and still fell short. The American system of multiple kinds of insurers (privately purchased on the open market, privately paid for by employers, plus the various government programs—Medicare, Medicaid, CHIP, military, VA, Indian populations—and concierge care, and the ever-popular emergency rooms for the self-pay) is no system at all.

Perhaps the country can take a collective deep breath and realize regardless of what the Supreme Court decides in June about King v. Burwell (will those four little words "established by the state" negate subsidies on the federal health insurance exchanges and destroy what little benefit has been derived from Obamacare) that the significance of this greatest accomplishment by the Obama Administration has been very overrated.

Obamacare did not really address the most basic of questions with regard to health care in America: Is it a right or a privilege?

Let the Congress decide that first and then come up with an appropriate strategy. This nonsense of curing the problem that does not exist while making far more problems got us just about nowhere.

Zwelling is the author of Red Kool Aid, Blue Kool Aid: How Partisan Politics and Greed Undermined the Value of Obamacare, a book about his experience on Capitol Hill during the debate about Obamacare, published by Franklin Scribes.

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Pediatrician Charged with Child Porn Possession Resigns from MD Anderson

By Paul Goldberg

A pediatric oncologist at MD Anderson Cancer Center is facing federal charges of one count of receiving and possessing child pornography.

Dennis Hughes, an associate professor of pediatrics, was arrested at his home June 5 after the Federal Bureau of Investigation found a thumb drive containing 8,200 downloaded files, the majority of which appeared to contain child pornography.

Hughes was arrested at his Pearland, Texas, home last Friday and charged with receipt and possession of child pornography in the U.S. District Court for the Southern District of Texas. Bond was set at $50,000 at a June 10 hearing.

On June 11, the Texas Medical Board suspended his medical license after determining that "his continuation in the practice of medicine poses a continuing threat to public welfare." Hughes then resigned from his job at MD Anderson.

"Dr. Hughes is presumed innocent," Hughes's attorney, Neal Davis, said in a statement. "He is charged federally with one count of receiving and possessing child pornography, NOT with making or distributing it. There is no allegation he had any improper contact with his patients or any other minors. He never has had any such improper contact."

He pled not guilty.

Hughes has worked at MD Anderson for the past 11 years, and his colleagues said they were surprised by the arrest. According to the NIH database, Hughes had three active NCI-funded projects in 2014. All three are focused on osteosarcoma.

MD Anderson has notified Hughes's patients, starting with those who saw him in the past two years. Initial communications to that first group of patients were calls and emails.

Now, the cancer center is reaching out to patients who saw Hughes earlier. This requires pulling data from records, confirming their accuracy, and developing lists for sending.

One of the emails sent to patients reads:

"Our patients' privacy and safety are first and foremost, which means we are committed to transparency and sharing information. As part of this commitment, we have some concerning news to share with you. Dr. Dennis Hughes, an associate professor

of Pediatrics, has been placed on administrative leave for allegations related to the possession of child pornography.

"We know this is difficult news to hear and we apologize for any distress caused by this communication. Because this is a very recent development, details are limited at this time. However, based upon the information we have received so far, we have no reason to believe the charges involve any of our patients or other MD Anderson staff.

"MD Anderson Children's Cancer Hospital faculty and staff are actively cooperating with law enforcement in their investigation. We also are conducting our own internal reviews."

An FBI agent's affidavit in support of a criminal complaint said Hughes had admitted to possessing and viewing child pornography since the late 1990s. The document, which is posted here, describes the circumstances of a search of the doctor's home and the circumstances under which files containing child pornography were found.

The Texas Medical Board said a temporary suspension hearing with notice will be held as soon as practicable with 10 days' notice to Hughes, unless the doctor chooses to waive the hearing.

In Brief

Karen Knudsen Named Director Of Sidney Kimmel Cancer Center at Thomas Jefferson University

KAREN KNUDSEN was named director of the **Sidney Kimmel Cancer Center at Thomas Jefferson University**.

Knudsen is the Hilary Koprowski Professor of Cancer Biology and Chair of Cancer Biology at Thomas Jefferson University, with joint appointments in the Departments of Urology, Radiation Oncology, and Medical Oncology.

Knudsen also served as the first Vice Provost for Thomas Jefferson University, overseeing and integrating basic and clinical research across all six schools at TJU.

Knudsen's research interests focus on genetic alterations that lead to prostate cancer progression and resistance to therapy.

During her eight years at Jefferson, Knudsen founded the Prostate Cancer Program of Excellence at SKCC, and also directs a multi-disciplinary think tank of scientists and clinicians called the Greater Philadelphia Prostate Cancer Working Group.

Knudsen's research on a newer chemotherapy treatment for prostate cancer, called cabazitaxel, revealed that this therapy could be useful for some patients earlier in their course of treatment. Her team also discovered a biomarker that may predict which patients would benefit from earlier treatment.

More recent studies from Knudsen's group connected alterations in DNA repair pathways with aggressive prostate cancers.

Knudsen serves on multiple national boards and committees associated with both basic and clinical research, including several for the American Association for Cancer Research, the Endocrine Society, the American Society for Clinical Oncology, and the Prostate Cancer Foundation. She is an associate editor for Endocrine-Related Cancer, and sits on the editorial boards of Molecular Cancer Therapeutics, the American Journal of Pathology, Molecular Endocrinology, and Oncogene. Knudsen also serves as editor-in-chief of the basic cancer research journal of the AACR, Molecular Cancer Research.

Knudsen currently serves on the NIH/NCI Parent Committee A, which is the peer-review arm of the NCI-designated Cancer Center Program, and has received numerous awards for her research, including the Ronald Ross Award for Excellence in Hormone-dependent malignancies from the Pacific Rim Breast and Prostate Cancer Research Organization, the Richard E. Weitzman Laureate Award from the Endocrine Society, the Sophie Yen Award for Distinguished Training in Translational Research, and the SWIU/SBUR Award for Excellence in Urologic Research.

ROBERTO PILI joined the **Indiana University Melvin and Bren Simon Cancer Center**. Pili will direct the genitourinary research program at the cancer center and serve as the medical director of the genitourinary clinical program at the IU Health Simon Cancer Center.

Pili is currently the Robert Wallace Miller Professor of Oncology at the Indiana University School of Medicine and a researcher at the IU Simon Cancer Center.

Pili said that the genitourinary research program's scientists will collaborate with researchers at the Purdue University Center for Cancer Research. The developing program will be co-led by Timothy Ratliff, the Robert Wallace Miller Director of the Purdue cancer center.

Previously, Pili was professor of oncology,

chief of the genitourinary section, and leader of the genitourinary program at Roswell Park Cancer Institute.

His laboratory research focuses on the development of novel therapeutic agents, including epigenetic agents such as histone deacetylase inhibitors and understanding their immunomodulatory effects. He also conducts phase I/II clinical trials of novel agents for the treatment of genitourinary malignancies.

MARY BECKERLE was appointed to the board of directors of **Johnson & Johnson**. Beckerle will serve on the board's Science, Technology & Sustainability Committee.

Beckerle has served as CEO and director of the Huntsman Cancer Institute at the University of Utah since 2006, and in 2009 was appointed as associate vice president for cancer affairs at the University of Utah. She joined the faculty of the University of Utah in 1986, and is a distinguished professor of biology and oncological sciences, holding the Ralph E. and Willia T. Main Presidential Professorship.

Beckerle has served on the NIH Advisory Committee to the Director and as the chair of the American Cancer Society Council for Extramural Grants. She currently serves on the Scientific Review Board of the Howard Hughes Medical Institute and the Scientific Advisory Boards of the National Center for Biological Sciences at the Tata Institute of Fundamental Research in India and the Mechanobiology Institute in Singapore. Beckerle is also currently on the board of directors of the American Association for Cancer Research, the Coalition for Life Sciences and the Huntsman Corporation.

She held a Guggenheim Fellowship at the Curie Institute in Paris, received the Utah Governor's Medal for Science and Technology in 2001, the Sword of Hope Award from the American Cancer Society in 2004 and is an elected fellow of the American Academy of Arts and Sciences.

THE PEW CHARITABLE TRUSTS named 22 early-career researchers as Pew scholars in the biomedical sciences—as well as five scholars for cancer research, funded in partnership with the Alexander and Margaret Stewart Trust.

The 2015 Pew-Stewart scholars for cancer research will pursue varied lines of inquiry in cancer biology, including the genetic basis of the disease, potential new therapeutics, and strategies that may bypass resistance to cancer-fighting drugs. They will receive four years of flexible funding.

The 2015 Pew-Stewart scholars for cancer research are:

• Mitchell Guttman, California Institute of Technology, biology

• Min Yu, University of Southern California, biology and regenerative medicine

• Adam de la Zerda, Stanford University, structural biology and electrical engineering

• Trever Bivona, University of California, San Francisco, medicine and hematology/oncology

• Cigall Kadoch, Dana-Farber Cancer Institute and Harvard Medical School; pediatric oncology, biological chemistry, and molecular pharmacology

The recipients join more than 600 scientists who have been selected as Pew scholars in the past 30 years.

Scholars in the 2015 class will investigate a range of topics from examining the role the microbiome plays in combating autoimmune disease, to exploring the molecules and neural circuits that dictate a mosquito's preference for humans over other animals.

The 2015 scholars in the biomedical sciences are:

• Theresa Alenghat, Cincinnati Children's Hospital Medical Center, Immunobiology

• Nicola Allen, Salk Institute for Biological Studies, Molecular Neurobiology

• Brenda Bloodgood, University of California, San Diego, Biological Studies and Neurobiology

• Jesse Bloom, Fred Hutchinson Cancer Research Center, Basic Sciences and Computational Biology

• Michael Cohen, Oregon Health and Science University, Physiology and Pharmacology

• Kimberly Cooper, University of California, San Diego, Cell and Developmental Biology

• Aaron Esser-Kahn, University of California, Irvine, Chemistry

• Gianna Hammer, Duke University, Immunology

• Michael Harms, University of Oregon, Chemistry and Biochemistry

• Christian Kaiser, Johns Hopkins University, Biology

• Daniel Kronauer, Rockefeller University, Insect Social Evolution

• Marcus Kronforst, University of Chicago, Ecology and Evolution

• Polina Lishko, University of California, Berkeley, Molecular and Cell Biology

• Qin Liu, Washington University, Anesthesiology, Opthalmology, and Visual Sciences

• Carolyn McBride, Princeton University, Ecology and Evolutionary Biology

• Nima Mesgarani, Columbia University, Electrical Engineering

• Douglas Millay, Cincinnati Children's Hospital Medical Center, Molecular Cardiovascular Biology

• Clarissa Nobile, University of California, Merced, Molecular and Cell Biology, Quantitative and Systems Biology

• Gary Patti, Washington University, Chemistry and Genetics

• Robert Schmitz, University of Georgia, Genetics

• Joshua Woodward, University of Washington, Microbiology

• Ke Xu, University of California, Berkeley, Chemistry

THE CANCER GENOME ATLAS Research Network, including more than 300 researchers from 44 institutions, found that molecular diagnostics are much more precise and reproducible than looking at tissue under a microscope for classification of diffuse gliomas.

The findings were published in The New England Journal of Medicine.

Researchers studied a group of six related lower-grade gliomas, using a large number of molecular platforms, and were able to determine that there were three well-defined tumor types based on this molecular analysis, rather than the six that had been described under the microscope.

Lead study author, Daniel Brat, a researcher and neuropathologist at Winship Cancer Institute of Emory University, said "the use of the biomarkers in the diagnosis of these forms of brain tumors will lead to a much more consistent manner of diagnosis and patient management. It will also allow us to investigate these tumors as unified groups in a way that should advance our understanding."

"This is important because the classification and grade that is given with these molecular tests will be more predictive of the tumor's behavior and we'll know whether a patient's disease requires more aggressive therapy or is sensitive to specific chemotherapies," Brat said.

THE AMERICAN ASSOCIATION FOR CANCER RESEARCH and **Bayer HealthCare** announced a partnership to expand AACR's Basic Cancer Research Fellowship Program for 2015.

The AACR-Bayer HealthCare Basic Cancer Research Fellowships represent a joint effort to provide critical support to postdoctoral and clinical fellows conducting basic cancer research at the earliest stages of their careers. Two fellowships are being provided through this partnership.

The 2015 recipients of the AACR-Bayer HealthCare Basic Cancer Research Fellowships are Mario Shields, of Cold Spring Harbor Laboratory; and Michelle Cicchini, of the University of Pennsylvania. Each grant will provide $55,000 for one year, beginning July 1.

AACR and Bayer will continue their partnership in 2016, where two new fellowship opportunities will be available: the AACR-Bayer HealthCare Prostate Cancer Research Fellowship and the AACR-Bayer HealthCare Hepatocellular Carcinoma Research Fellowship.

The research proposed for funding may be basic, translational, clinical, or epidemiological in nature and must have direct applicability and relevance to either prostate cancer or hepatocellular carcinoma. These funding opportunities will be open to applications in the fall of 2015. All decisions regarding the review and selection of the submitted applications will be made by the AACR Scientific Review Committee.

THE SCRIPPS MERCY O'TOOLE Breast Care Center opened on the campus of **Scripps Mercy Hospital San Diego**. The $5.3 million facility is located on the second floor of the Scripps Medical Building, and replaces the temporary breast health facility that opened last year near Scripps Mercy Hospital.

"We are grateful to the Theresa and Edward O'Toole Foundation and the Menard Family Foundation for supporting the expansion of breast care services in the communities that we serve," said William Stanton, medical oncologist and medical director of the Scripps Cancer Center at Scripps Mercy Hospital's San Diego campus.

The O'Toole Breast Care Center provides convenient access to residents of central San Diego neighborhoods, including Hillcrest, Mission Hills, downtown San Diego, Bankers Hill, City Heights, North Park, Normal Heights, Mission Valley and Point Loma.

The 3,612-square-foot facility has several specialized rooms for services such as: mammography, including breast tomosynthesis; dexa scans for bone density measuring; gynecologic and obstetric imaging; and pre-surgery needle localization using mammography, stereotactic-guided or ultrasound-guided procedure.

THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY published **Practical Tips for the Oncology Practice 6th Edition**, a comprehensive business and management resource for oncology practices on June 8.

This edition includes: new guidance and insight into the coverage and billing of oncology-related services, clinical trials, and drugs; recent updates to Medicare regulations, reimbursements, ICD-9 and ICD-10 codes; safe drug handling guidelines and requirements; latest information on Physician Quality Reporting Programs, Medicare's Physician Quality Reporting Systems and the Value Based Modifier; and an overview of the Medicare appeals process.

The guide can be downloaded onto E-readers, mobile devices and desktop computers from the ASCO University online bookstore for $275. ASCO members will receive a 20 percent discount.

CHRIS4LIFE COLON CANCER FOUNDATION and **SMART PATIENTS** launched **DATABLUE**, a clinical trial database that helps colon cancer patients navigate trial processes on June 4.

DATABLUE recommends clinical trials to patients based on their information. It has a user-friendly interface that simplifies the screening process, translates protocols into everyday language, and allows patients to accelerate their trial process, according to Chris4Life and Smart Patients.

"We are so pleased to partner with Smart Patients in building this unique portal to help colon cancer patients with their journey of treatment options," Chris4Life Founder & CEO Michael Sapienza said in a statement. "Many individuals in the industry are working tirelessly to find a cure, with clinical trials providing the path through which a cure may be found. We hope to move the percentage participation needle up beyond 3 percent in order to achieve success, and make trials more accessible to colorectal cancer patients and caregivers."

THE CANCER LETTER received a first place **2015 Dateline Award for Excellence in Local Journalism** from the Society of Professional Journalists June 9. The award recognizes Matthew Ong's series "Power Morcellation: A Hazardous Practice" as the winner in the Newsletter, Washington, D.C., category.

"An excellent job of dealing clearly and comprehensively with a complex issue," the judges noted.

Ong's series, which includes an interview documentary, can be found here.

Drugs and Targets

Lenvatinib Launched in U.K. For Advanced Thyroid Cancer

Lenvima (lenvatinib) launched in the U.K. as a treatment option for adult patients with progressive locally advanced or metastatic, differentiated (papillary, follicular, Hürthle cell) thyroid carcinoma, refractory to radioactive iodine.

Lenvatinib demonstrated significantly prolonged progression-free survival in RAI refractory DTC versus placebo. Lenvatinib showed a median 18.3 months progression free survival PFS versus 3.6 months for placebo (HR=0.21; 99% CI, 0.14-0.31; $p<0.0001$).

In addition, the study underlines the rapid response of lenvatinib, with a median time to first objective response of two months.

The SELECT study, published in the New England Journal of Medicine, is a randomized, double-blind, multicenter trial for people with progressive radioactive iodine refractory differentiated thyroid cancer (n=392). Lenvatinib significantly improved objective response rate versus placebo (64.8 vs. 1.5 percent; $p<0.0001$).

For lenvatinib, the most common treatment related adverse events were hypertension, diarrhea, fatigue, decreased appetite, decreased weight, and nausea.

"The launch of Lenvima represents great news for both Eisai and for patients who will now have access to this significant new treatment. Lenvima is a drug that was developed in the UK, will be manufactured in the UK and has now been launched first in the UK, something we at Eisai are very proud of," said Gary Hendler, president and CEO of Eisai EMEA and president of the Eisai Oncology Global Business Unit.

Lenvatinib is an oral molecular tri-specific targeted therapy that possesses a potent selectivity and a binding mode different to other tyrosine kinase inhibitors. Lenvatinib simultaneously inhibits the activities of several different molecules including vascular endothelial growth factor receptors, fibroblast growth factor receptors, RET, KIT and platelet-derived growth factor receptors.

Lenvatinib has been approved for the treatment of refractory thyroid cancer in the United States, Europe and Japan, and has been submitted for regulatory approval in Switzerland, South Korea, Canada, Singapore, Russia, Australia and Brazil. Lenvima was granted Orphan Drug Designation in Japan for thyroid cancer, in the United States for treatment of follicular,

medullary, anaplastic, and metastatic or locally advanced papillary thyroid cancer and in Europe for follicular and papillary thyroid cancer.

Merck Canada Inc. announced that Keytruda (pembrolizumab) was authorized for sale with conditions by Health Canada.

Keytruda is indicated for the treatment of patients with unresectable or metastatic melanoma and disease progression following ipilimumab therapy and, if BRAF V600 mutation positive, following a BRAF or MEK inhibitor.

The product has been approved in Canada under the Notice of Compliance with Conditions policy on the basis of promising evidence of clinical effectiveness and pending the results of trials to verify its anticipated benefit. Keytruda is the first of anti-PD-1s approved in Canada.

FDA granted an orphan drug designation for APTO-253 for the treatment of acute myeloid leukemia.

APTO-253, a first-in-class inducer of the KLF4 gene, is in a phase Ib clinical trial in patients with AML, high-risk myelodysplastic syndrome and other hematologic malignancies in which KLF4 silencing is reported as operative, according to the drug's sponsor, Aptose Biosciences Inc.

Epigenetic suppression of the Krüppel-like factor 4 gene has been reported in the scientific literature as a transforming event in AML. APTO-253 has demonstrated a favorable safety profile with no evidence of suppression of the normal bone marrow. Preclinical studies have shown potent single-agent activity to kill AML cells and strong synergy as part of a combination strategy with various marketed and investigational agents.

If APTO-253 is approved to treat AML, the orphan drug designation provides Aptose with seven years of marketing exclusivity.

Janssen Research & Development initiated the rolling submission of its Biologic License Application for daratumumab to FDA for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a proteasome inhibitor and an immunomodulatory agent, or who are double refractory to a PI and an IMiD.

Daratumumab, an investigational human anti-CD38 monoclonal antibody, received Breakthrough Therapy Designation by the FDA for this set of patients in May 2013. A rolling submission allows the company to submit portions of the regulatory application to the FDA as they are completed.

In August 2012, Janssen and Genmab A/S entered into an agreement which granted Janssen a worldwide exclusive license to develop, manufacture and commercialize daratumumab. With the exception of one study sponsored globally by the French multiple myeloma cooperative group, Intergroupe Francophone du Myelome, Janssen is the global sponsor of all current and future clinical studies for daratumumab.

The regulatory submission for daratumumab will be primarily supported by data from the phase II MMY2002 (SIRIUS) monotherapy study announced in May 2015 at the annual meeting of the American Society of Clinical Oncology, along with additional data from four other studies, including the phase I/II GEN501 monotherapy study.

MD Anderson Cancer Center and Nektar Therapeutics announced a research collaboration that includes a phase I/II clinical study to evaluate NKTR-214, a CD122-biased cytokine designed to preferentially stimulate production of CD8-positive T cells.

CD122, which is also known as the Interleukin-2 receptor beta sub-unit, is a key signaling receptor that is known to increase proliferation of these effector T cells.

"We are certain that cytokines are an essential pillar of immunotherapy, along with checkpoint inhibitors, adoptive T cell therapy and cancer vaccines," said Patrick Hwu, Division Head of Cancer Medicine at MD Anderson. "Through clinical studies, we will explore this new cytokine's potential to preferentially activate an established target, the IL-2 receptor beta or CD122, in order to stimulate tumor cell killing within the tumor microenvironment."

The agreement covers a study to evaluate NKTR-214 in a variety of tumor types as a monotherapy and in combination with other therapies, including PD-1 pathway inhibitors. Nektar and MD Anderson expect to initiate the first dose-escalation clinical study later this year. The two organizations will also conduct translational research to identify predictive biomarkers that can be used in the future development of NKTR-214.