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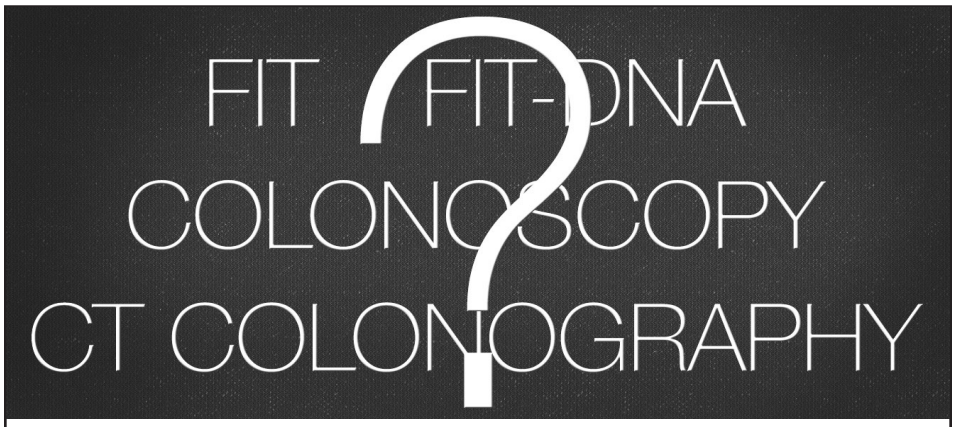

CT Colonography and Stool DNA Fail to Make USPSTF A-List

By Paul Goldberg

CT colonography and stool DNA failed to get on the list of preferred tools for screening for colorectal cancer.

A draft guideline from the U.S. Preventive Services Task Force released Oct. 6 calls for using one of three strategies:

• Fecal immunochemical test or high-sensitivity guaiac-based fecal occult blood test every year;

• Flexible sigmoidoscopy every ten years, plus FIT every year; or

• Colonoscopy every ten years.

(Continued to page 2)

Capitol Hill

Collins to Congress: A Flat, Year-long CR Would Be "Devastating" to NIH Research

By Conor Hale

If Congress passes another year-long, flat-funding resolution, the effect on NIH "would be simply devastating," Director Francis Collins told a Senate appropriations subcommittee during a hearing Oct. 7.

"I can't emphasize enough how much we are worried about this," Collins said, sitting alongside NCI Acting Director Douglas Lowy and other institute directors.

(Continued to page 6)

In Brief

Lindahl, Modrich and Sancar Win Nobel Prize For Research on DNA Repair Mechanisms

THE NOBEL PRIZE IN CHEMISTRY for 2015 was awarded to **Tomas Lindahl, Paul Modrich** and **Aziz Sancar**, for their mechanistic studies of DNA repair, by the Royal Swedish Academy of Sciences.

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CT Colonography and Stool DNA Fail to Make USPSTF A-List

(Continued from page 1)

Screening with any one of these three strategies received an "A," the highest grade, for ages 50 to 75 and a "C" for ages 76 to 85.

The updated guideline makes a few changes, but is consistent with its previous iteration, published in 2008 (The Cancer Letter, Oct. 8, 2008).

In 2008, CT colonography and stool DNA received "I" grades, which indicate that evidence is insufficient. Seven years later, they are getting no grade at all, and are being lumped together as "alternative tests."

"Screening with computed tomography colonography and multitargeted stool DNA testing may be useful in select clinical circumstances," the guidelines state. "However, there is less mature evidence to support these methods, resulting in greater uncertainty about their net benefits and the most appropriate situations in which to use them."

Under the Affordable Care Act, private insurers would be obligated to cover screening modalities that receive A or B grades from USPSTF, though the task force does not issue guidelines based on coverage considerations. (The Cancer Letter, Oct. 2). Medicare makes its decisions separately.

Evidence-based medicine doesn't provide a path to making friends in America, and ACA makes the miniscule USPSTF the target for attacks from professional societies and patient groups that advocate for screening.

The task force's C grade for mammography screening of women between 40 and 50 has been famously overruled by Congress and HHS (The Cancer Letter, April 24).

Various legislative proposals seek to defang the task force by adding representatives from subspecialty groups and by moving its offices from the Agency for Healthcare Research and Quality, which is targeted for elimination by conservative legislators (The Cancer Letter, June 19, June 26).

"It is unclear how these draft USPSTF recommendations would affect coverage and resulting patient access, given that the USPSTF did not propose grades for specific screening technologies," the American College of Radiology said in a statement.

"CT colonography is an American Cancer Society recommended screening test. Studies in the *New England Journal of Medicine* and elsewhere prove CT colonography is comparably accurate to optical colonoscopy—including in those ages 65 and older. President Obama chose to have a CT colonography in his first checkup as commander-in-chief."

The price of shares of Exact Sciences Corp. (EXAS) immediately plunged by about 47 percent Oct. 6, after the USPSTF guideline. The stock hit a new 52-week low of $9.86, down from $18.53 the night before. The stock has continued to decline and is trading at $7.80 at this writing. The company's 52-week high was $32.85.

"This decision was different that what we and most people expected," said Kevin Conroy, president, CEO and chairman of the board of Exact Sciences.

In the Oct. 6 conference, Conroy said the USPSTF recommendation represents "a changed framework for how tests are graded, and Cologuard [the company's test] today is included in a distinctly new category, which is not the category that Exact Sciences expected."

This category of tests—called "alternative tests"—would be used in circumstances that the task force doesn't define. "We believe they will be defined in clinical practice, and we believe that the circumstances in which Cologuard is being used in today include the many patients who can't for medical reasons or won't adhere to either colonoscopy or FIT screening recommendations," Conroy said.

Cologuard was approved by FDA in August 2014 (The Cancer Letter, March 28, 2014, Sept. 5, 2014). Medicare's "crosswalk" price for the test is $492.72. After a year on the market, at least 20,000 physicians have ordered at least one test, with a total of approximately 100,000 tests, Conroy said.

"We have no reason to believe that the USPSTF decision will impact our strong launch," he said to analysts.

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Population	Recommendation	Grade
Adults ages 50 to 75 years	The USPSTF recommends screening for colorectal cancer starting at age 50 years and continuing until age 75 years. The risks and benefits of different screening methods vary.	A
Adults ages 76 to 85 years	The decision to screen for colorectal cancer in adults ages 76 to 85 years should be an individual one, taking into account the patient's overall health and prior screening history. • Adults in this age group who have never been screened for colorectal cancer are more likely to benefit. • Screening would be most appropriate among adults who: 1) are healthy enough to undergo treatment if colorectal cancer is detected, and 2) do not have comorbid conditions that would significantly limit life expectancy.	C

The Colon Cancer Alliance, an advocacy group, said the draft guidance would "reinforce known barriers to screening" and, with the same tests recommended, would result in "stagnant screening rates."

"In this draft recommendation, the USPSTF does not recommend the FIT-DNA test due to the potential 'harm' from people having a colonoscopy as a result of a false positive and instead endorses FIT which misses many cancers as it only looks for the presence of blood in the stool," the alliance said in a statement. "The health risk from having a colonoscopy is extremely small (FDA estimates 0.68% adverse event rate); however the risk from colon cancer diagnosis could be fatal. The USPSTF appears to believe that the risk of having a colonoscopy is greater than missing the presence of colon cancer by a test that is already FDA approved."

CT colonography should also be on the list, the advocacy group said. "President Obama was screened using CT colonography to avoid unnecessary sedation," the alliance said. "CT colonography is recommended for the leader of the free world, but not recommended for other Americans by USPSTF."

By not giving out grades for every screening method that comes to its attention, the agency could be signaling that it's going to limit its gatekeeping role.

Screening for colon cancer is unique, because so many screening methods are available and it may not be practical to grade all of them. Inclusion of sigmoidoscopy in the draft guidelines is noteworthy, because this procedure is mostly unavailable in the U.S. In fact, medical schools and residency training programs no longer teach students to perform it.

Why Not:

USPSTF described its rationale for excluding colonography and FIT-DNA:

• **CT Colonography**—The USPSTF found no studies that assessed the impact of screening with CT colonography on cancer incidence, morbidity, quality of life, or mortality. Although nine studies evaluated the sensitivity and specificity of CT colonography compared with colonoscopy to detect colorectal adenomas, none were designed to determine its diagnostic accuracy to detect colorectal cancer (the overall number of cancer cases in each study was limited). Empiric evidence on the optimal screening interval, if any, is lacking. Cancer Intervention and Surveillance Modeling Network modeling suggests that screening every five years with CT colonography (assuming colonoscopy followup for lesions measuring ≥6 mm) from ages 50 to 75 years could potentially yield approximately the same number of life-years gained, with a similar balance of benefits and harms, as the recommended strategies previously listed. However, CT colonography often requires cathartic bowel preparation; this burden is not captured in the primary proxy measure of harms as lifetime number of colonoscopies.

Extracolonic findings on CT colonography are common, occurring in approximately 40 to 70 percent of screening examinations. About 5 to 37 percent of these extracolonic findings require diagnostic follow-up, and about 3 percent need definitive treatment. These findings have the potential for both benefit and harm. Potential harms include additional diagnostic testing to determine that an abnormality is of no clinical importance, as well

Source: USPSTF

Screening Modality	Frequency	Other Considerations
FIT or high-sensitivity gFOBT	Every year	Requires the fewest lifetime colonoscopies (a proxy for harms). Does not require bowel cleanout, anesthesia, or transportation to and from the screening examination (test is performed at home).
Flexible sigmoidoscopy with FIT	Flexible sigmoidoscopy every 10 years plus FIT every year	Potentially attractive option for persons who want endoscopic screening but wish to limit exposure to colonoscopy. May also be useful when access to colonoscopy is geographically limited.
Colonoscopy	Every 10 years	Requires less frequent screening. Screening and diagnostic follow-up of positive results can be performed during the same examination.

as treatment of findings that may never pose a threat to a patient's health or even become apparent without screening (i.e., overdiagnosis and overtreatment). Radiation-induced cancer is a potential long-term concern with repeated use of CT colonography. No studies directly measured this risk, but radiation exposure during the procedure appears to be low, with a maximum of about 7 mSv per examination. In comparison, annual background radiation exposure in the United States is 3 mSv per year per person. Although seven new studies have examined the potential harms associated with CT colonography since the prior USPSTF review, high-quality evidence remains lacking to draw clear conclusions about the ultimate clinical impact associated with the detection and subsequent workup of extracolonic findings. Given the frequency with which these incidental findings occur, it is difficult to accurately bound the potential net benefit of this screening test without this information.

• FIT-DNA—The USPSTF found no studies that assessed the impact of screening with FIT-DNA on cancer incidence, morbidity, quality of life, or mortality. One study compared the sensitivity and specificity of the only FIT-DNA screening test available in the United States with FIT alone and colonoscopy for the detection of colorectal cancer and found that FIT-DNA was more sensitive but less specific than FIT alone. Evidence on the optimal screening interval, if any, is lacking. CISNET modeling suggests that annual screening with FIT-DNA from ages 50 to 75 years could potentially yield approximately the same number of life-years gained as the recommended strategies previously listed. However, compared with other stool-based screening tests and screening with colonoscopy every 10 years, FIT-DNA requires a larger number of lifetime colonoscopies (a proxy for the harms of screening) per life-year gained.

Harms associated with FIT-DNA largely arise from diagnostic colonoscopy performed after positive screening results. Since the specificity of FIT-DNA is lower than that of FIT, the number of false-positive results, and the likelihood of experiencing an adverse event related to diagnostic colonoscopy, are increased. A theoretical concern about FIT-DNA is whether its use might lead to more frequent and invasive follow-up testing in persons who are not at increased risk of colorectal cancer because of patient or clinician concerns about abnormal DNA results. There are no data that evaluate how to implement FIT-DNA into a longitudinal colorectal cancer screening program.

Multitargeted stool DNA testing can be viewed simply as a more sensitive but less specific stool-based test than FIT. However, the theoretical advantage of the test is the stool DNA component. At present, there is only one fair-quality study that compares the sensitivity and specificity of a single FIT-DNA test with FIT. While modeling can be used to understand the impact of the test's reduced specificity and increased false-positive rate, empiric evidence is lacking on appropriate follow-up of abnormal results, making it difficult to accurately bound the potential net benefit of this screening test.

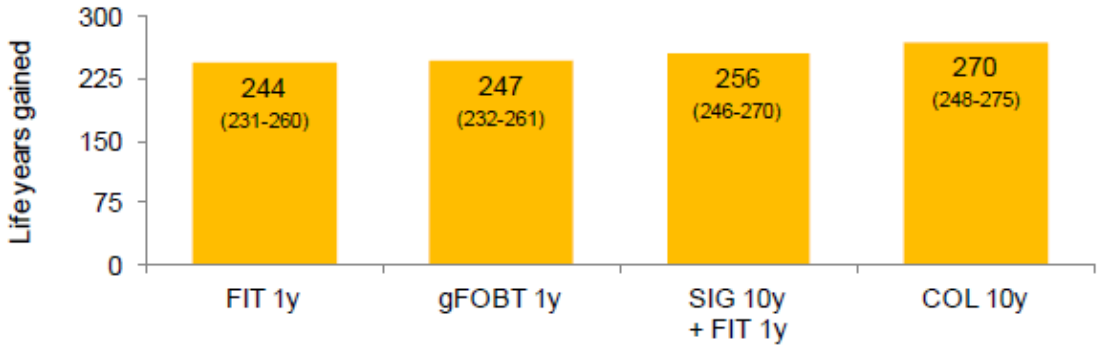
NCI's Kramer Finds Recommendation Reasonable

Barnett Kramer, director of the NCI Division of Cancer Prevention, said "gaps in evidence" identified by the USPSTF draft recommendation on stool DNA and colonography reflect the need for longitudinal data on sensitivity, specificity, as well as the balance of benefits and harms.

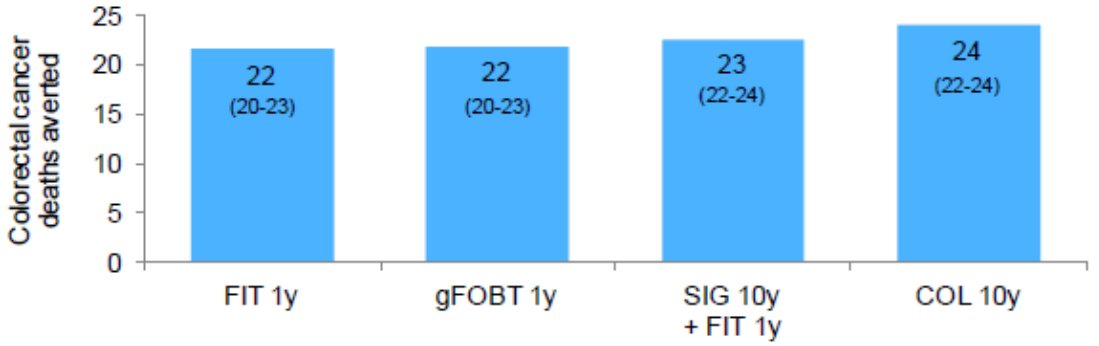
"There are important gaps in evidence and there isn't any longitudinal evidence about the balance of benefits and harms—yet," said Kramer, who wasn't involved in drafting the recommendations. "Obviously, the stool DNA test would reduce deaths from colorectal cancer, because the test includes the fecal blood test. It's composed of a FIT plus DNA test. It appears to have substantially lower specificity, yielding more false positives and we don't

Draft: Figure. Benefits, Harms, and Burdens of Recommended Screening Strategies Over a Lifetime

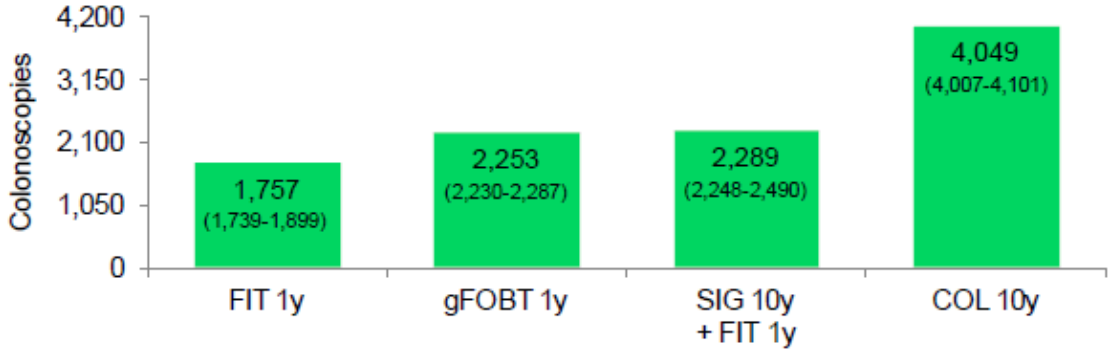
A. Benefit: Life Years Gained, per 1,000 Screened



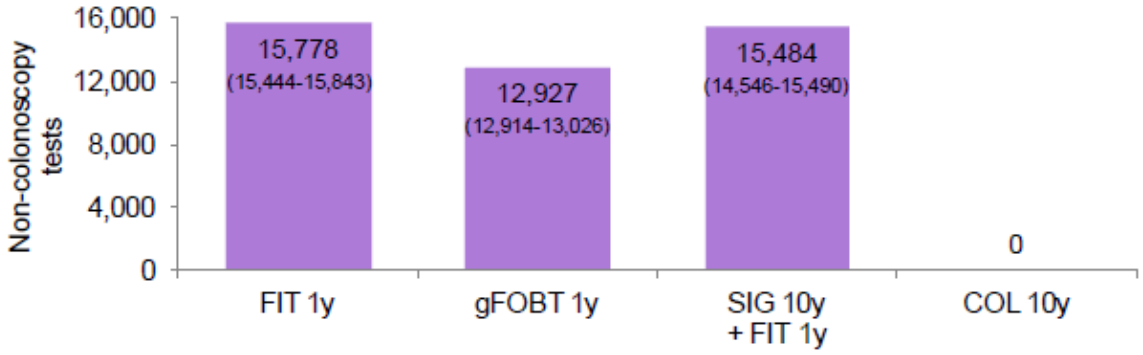
B. Benefit: Colorectal Cancer Deaths Averted, per 1,000 Screened



C. Harms (Proxy): Lifetime Number of Colonoscopies, per 1,000 Screened



D. Additional Burden: Lifetime Number of Non-Colonoscopy Tests, per 1,000 Screened



Source: USPSTF

even know how many cumulative false-positives there would be in a screening program, because the published literature only has a one-time test."

"There is strong evidence that favors all three of the strategies that USPSTF recommended," Kramer said. "However, the tests have different harms associated with them. Fecal blood testing being the least harm, colonoscopy being the greatest harm.

"And since they've never been compared yet head to head in a mature, published randomized trial, it's reasonable to identify all three options as standard for an informed patient to take. Any of the three really would lower the risk of dying of colorectal cancer.

"The USPSTF also points out correctly that none of these tests have been shown to increase life expectancy. None have been shown to decrease all-cause mortality, even though they have all been shown to reduce colorectal cancer deaths."

Capitol Hill

Collins: Year-long CR Would Be "Devastating" to NIH Research

(Continued from page 1)

"The Precision Medicine Initiative, for instance, would basically have to go into the freezer, or on mothballs, or whatever the appropriate discouraging metaphor would be," he continued, describing the push for genomic research and the plan to form a million-member research cohort over the next four years, as well as the consequences for a two-year-old effort to map and understand the human brain.

"We would just be at the point of starting the effort to enroll a million Americans in this unprecedented study and carrying out exciting new studies in cancer genomics—and those would basically have to go on hold. That would be enormously disappointing.

"Similarly, the BRAIN Initiative, which is on this exciting ramp up, would basically have to take a pause, just at the point when the momentum is building."

Congress recently passed a continuing resolution designed to keep the federal government operating for nine more weeks, when new funding will have to be passed.

"We can struggle along with a CR until Dec. 11, but if it's a year-long CR without an anomaly [in funding for NIH], it's going to be a dark day—indeed, a dark year," Collins said.

Both Collins and Lowy described how the NIH and NCI's flagship research projects would require more funding in order to progress.

"This is really a critical juncture right now, because we have opportunities for long term responses" in precision medicine studies focused on immunotherapies, Lowy said.

Collins described a sense of optimism that the House and the Senate would increase funding for its research: "We've been heartened greatly by the actions of this committee, and the similar committee in the House, to believe that we may have a chance to do those things."

Indeed, the NCI's bypass budget for 2017 asked for 7-percent increases annually over the next decade, doubling the institute's budget by 2026 (The Cancer Letter, Sept. 18).

"Here we are in a circumstance where perhaps, emboldened by the enthusiasm we've seen in both the Senate and the House in the FY16 budget process, we have a number of very exciting initiatives that we would like to launch," Collins said.

What Would You Do with $3 Billion?

Senators on both sides of the aisle were receptive to the idea of increased funding for the NIH.

Sen. Barbara Mikulski (D-Md.), vice chairwoman of the Senate Appropriations Committee, asked each of the institute directors to name three things they would be able to do with the funding increases provided for in the president's budget proposal, which called for nearly 6 percent increases in research and development, and how that would affect young investigators.

"We at NCI are in the process of trying to develop new approaches to enhance their ability to move from being graduate students and post-doctorate fellows to starting their own laboratories," said Lowy.

"The areas that we would invest in would be cancer prevention, cancer screening and cancer treatment using molecular precision medicine approaches, which have enormous potential in those areas. And I would highlight immunotherapy…and its potential for improved responses, decreased side effects, and scalability."

"One of the things I wanted to do today was get on the record the kinds of things you would do," said Sen. Roy Blunt (R-Mo.), chairman of the Senate Labor, Health and Human Services and Education Appropriations Subcommittee.

"Now, strictly speaking to Sen. Mikulski's question, the president asks for half of the increase the committee has proposed you get—so I'm going to look very closely at all the things you said you'd do if you had the president's number, and assume I can multiply that by two, and that would be the things you could do if you had the number the committee's proposing that

you get at NIH," said Blunt.

"Say you had $3 billion more," Sen. Richard Shelby (R-Ala.) asked Collins. "What could you do with it, as far as investigating, and hoping to turn those results into better health? What would $3 billion do—let's just use that [number]; I made it up. I hope we could do something for you. What could you do for us?"

"What would it do for America and for the world?" said Collins. "Senator, I appreciate the question. It's a lovely thing to contemplate. Because as you've heard, we've lost, over the past 12 years, about 22 percent of our purchasing power.

"This would be about a 10 percent increase—it wouldn't quite get us back to where we were in 2003, but oh my gosh would it be an enormous shot in the arm to a community that has such talent, and such energy, and is basically being squeezed to the point where a lot of the innovation that we could be doing is just not happening.

"The Precision Medicine Initiative, which we hope to start in FY16, which I think has a lot of bipartisan support—and which the scientific community, after many workshops and a working group that debated about this, is very jazzed about—we can't start that if we have a year-long [continuing resolution]. But we could start it and we could ramp it up much faster if we had this kind of curve to work with, as far as research.

"Put all that together," Collins said, "and with $3 billion—well, you know, let's try it! Let's try the experiment and see how that turns out!

"I promise you that it would be amazing."

Lowy's Vision

Sen. Gerald Moran (R-Kan.) asked Douglas Lowy to describe his vision for NCI as acting director, as well as deliver a summary of the pediatric MATCH trial:

LOWY: "The pediatric MATCH trial is currently under development, and it does essentially for pediatric cancer research what the adult MATCH trial that started two months ago is doing for adults who have advanced cancer for which there is no standard treatment.

"It puts the molecular abnormality of the patient front and center, rather than the origin in the body of where it occurs. And it takes drugs that are off the shelf, either experimental drugs or those that have been approved for other uses, and it tests them in these other ways for cancer where they are not yet approved. The goal is to improve the outlook for these patients, and it is one of the parts of the oncology portion of the Precision Medicine Initiative that people have been talking about.

"The overall vision for NCI is to support basic research, as we have done historically. To invest in precision medicine, not just in the areas of cancer treatment, as is occurring with the oncology portion of the Precision Medicine Initiative, but also to emphasize precision medicine in the area of cancer prevention and cancer screening: understanding better the causes of cancer, and how cancer comes about, and, in addition, to put a focus on health disparities in cancer.

"Unfortunately, there are many different kinds of cancer where certain underrepresented minorities have a much higher incidence of mortality, and we need to treat these populations as we would any high-risk population—to understand the biology, the lifestyle factors, and the utilization of medical utility, and to try to mitigate these factors for any high risk population. These are some of the important areas that we are looking forward to making progress in."

CMS Issues Updated Pricing For Clinical Lab Fee Schedule

Centers for Medicare and Medicaid Services issued updated pricing determinations for the Clinical Laboratory Fee Schedule, which reversed a payment cut for the Oncotype DX breast cancer test.

The payment rate for Oncotype DX, sponsored by Genomic Health, has been at $3,416, but CMS was taking steps to drop it to $2,900 (The Cancer Letter, Oct. 2). Genomic Health officials said CMS had notified the company on Oct. 6 that the price of Oncotype DX will remain unchanged throught 2016. In 2017, market-based rates under the Protecting Access to Medicare Act are expected to replace the current Medicare CLFS.

"We are pleased that CMS quickly revised its final pricing determination for the Oncotype DX breast cancer test to reflect the MAC-established rate as well as the factors set forth by Medicare to establish payment amounts, such as market rates and resources," Kim Popovits, chairman of the board, CEO and president of Genomic Health, said in a statement.

Asked by The Cancer Letter why the price drop was proposed and why it was reversed, CMS officials said that this was a new code, which required CMS to determine how to pay for it. The payment proposal was still open to public comment at a time when the agency reconsidered.

Noridian Healthcare Solutions, the Medicare Administrative Contractor that processes Genomic Health's claims, set this price for Oncotype DX in 2006.

The previous rate appears to have been set without factoring in the states served by Noridian, and Bruce Quinn, an expert on Medicare coverage, speculated in his blog that CMS may have miscalculated the rate.

Letter to the Editor

Dear Editor,

We are writing to clarify a few points in your Oct. 2 article, "CMS to Trim Spending on Diagnostic Lab Tests," as it mistakenly intertwines two issues.

On Friday, Sept. 25, 2015, the Centers for Medicare & Medicaid Services (CMS) released three separate items related to molecular diagnostics: 1) the 2015 Final Gapfill rates; 2) the Preliminary Determinations for the Calendar Year 2016 Clinical Laboratory Fee Schedule; and, 3) the Medicare Clinical Diagnostic Laboratory Tests Payment System Proposed Rule (as required under PAMA Section 216).

In the 2015 Gapfill rates the payment rate for Oncotype DX test for breast was reduced. Yesterday, CMS announced a technical correction to this payment rate and Genomic Health issued a release.

In the CY2016 Preliminary Determinations, CMS recommended payment rates that, if finalized, would represent drastic reductions of 30% up to 90% in payment rates for several well-established, Medicare covered advanced diagnostic laboratory tests. CMS has since announced a public expert Advisory Panel meeting on October 19th. The Coalition and member companies plan to present and we believe this an opportunity for CMS to correct the rates and issue a Final Determiantion of gapfill for 2016. The gapfill recommendation would have the effective of leaving pricing to the Medicare contractors, thus allowing MACs to continue with their current pricing. We think this is consistent with CMS policy, the August Advisory Panel recommendation, and the PAMA statute.

In the Clinical Diagnostic Laboratory Tests Payment System Proposed Rule CMS included a restrictive definition for Advanced Diagnostic Laboratory Tests (ADLTs) that would exclude tests based on an analysis of proteins. These advanced diagnostic tests provide physicians with specific information for managing the care of patients with complex conditions, like cancer, heart transplants, cardiovascular disease and rheumatoid arthritis. C21 plans to submit comments in the next month on the Proposed Rule.

Sincerely,

The Coalition for 21st Century Medicine

In Brief

Lindahl, Modrich, Sancar Win 2015 Nobel Prize in Chemistry

(Continued from page 1)

Lindahl is an emeritus group leader at the Francis Crick Institute, and the first director of Cancer Research UK's Clare Hall Laboratories from 1986 to 2005. Lindahl was previously awarded the U.K. Royal Society's Royal Medal in 2007, the Copley Medal in 2010, and the INSERM Prix Etranger in 2009.

Modrich is the James B. Duke Professor of Biochemistry and a member of the Duke Cancer Institute at the Duke University School of Medicine, as well as a Howard Hughes Medical Institute investigator. He is a member of the Institute of Medicine and the National Academy of Science, and a fellow of the American Academy of Arts and Sciences.

Sancar is the Sarah Graham Kenan Professor of Biochemistry and Biophysics at the University of North Carolina, Chapel Hill. He is a member of the American Academy of Arts and Sciences, the National Academy of Sciences, and the Turkish Academy of Sciences. He previously received the National Science Foundation Presidential Young Investigator Award, the NIH MERIT Award, and the Vallee Award from the American Society for Biochemistry and Molecular Biology.

The prize includes 8 million Swedish krona, over $981,000, split equally among the recipients.

The prize was awarded for their work in mapping, at a molecular level, how cells repair damaged DNA and safeguard genetic information, and its implications in the development of cancer treatments.

From the Royal Swedish Academy:

"In the early 1970s, scientists believed that DNA was an extremely stable molecule, but Tomas Lindahl demonstrated that DNA decays at a rate that ought to have made the development of life on Earth impossible. This insight led him to discover a molecular machinery, base excision repair, which constantly counteracts the collapse of our DNA.

"Aziz Sancar has mapped nucleotide excision repair, the mechanism that cells use to repair UV damage to DNA. People born with defects in this repair system will develop skin cancer if they are exposed to sunlight. The cell also utilizes nucleotide excision repair to correct defects caused by mutagenic substances, among other things.

"Paul Modrich has demonstrated how the cell corrects errors that occur when DNA is replicated during cell division. This mechanism, mismatch repair,

reduces the error frequency during DNA replication by about a thousand-fold. Congenital defects in mismatch repair are known, for example, to cause a hereditary variant of colon cancer."

The academy's compiled scientific background regarding this year's Nobel Prize in Chemistry can be found here.

ALEXANDER EGGERMONT, general director of **Institut Gustave Roussy** since 2010, has had his appointment as head of the institute renewed by the French Minister of Health for another five years. The institute is one of the largest health centers in Europe dedicated to oncology.

The past five years has seen a large investment program at the institute: "We increased our workload by 15 percent and established more than 440 posts in care and research, while maintaining budgetary balance and improving our financial situation. Almost 113 million euros were invested to facilitate rapid access to the latest therapeutic developments and to improve the quality of care for our patients," said Eggermont.

This included: the construction of a building dedicated to Molecular Medicine, the creation of the Drug Development Department, architectural renovation of the infrastructure of departments such as that of pediatrics and the purchase of major equipment for surgery, imaging and radiotherapy. In addition, there has been an amalgamation with the Chevilly-Larue Hospital Centre and the development of partnerships with foreign centers.

Eggermont plans to develop its Cancer Campus and the PRECAN platform for preclinical research in oncology. Through its involvement in Cancer Campus, Gustave Roussy plays a role in the Grand Parc Campus ZAC and is a driving force in the Grand Paris Company, according to the institute.

His objectives also include the development of the relationship with the Paris-Sud University, the future Paris-Saclay, and to establish a Department of Oncology within the Faculty of Medicine.

VICTORIA SEEWALDT was named the Ruth Ziegler Chair in Population Sciences at **City of Hope**. Seewaldt will also serve as the associate director of the comprehensive cancer center.

Previously, she was a professor of medicine at Duke University and leader of the Comprehensive Cancer Breast and Ovarian Cancer Program. She also founded the institution's community outreach program for underserved women.

Seewaldt will lead the Breast Cancer Early Detection and Health Disparities Program at City of Hope, operating a clinic for women at high risk of breast and ovarian cancers, and emphasizing clinical trials that focus on high-risk women.

NYU LANGONE MEDICAL CENTER established a program in biologics research, appointing **Shohei Koide** to lead the new initiative.

Koide will join NYU Langone March 1, 2016 as director of cancer biologics at the Laura and Isaac Perlmutter Cancer Center.

"No other academic medical institution on the East Coast has a major presence in biologics research," said Dafna Bar-Sagi, professor of biochemistry and molecular pharmacology, senior vice president and vice dean for science at NYU Langone.

Koide has served on the faculty at the University of Chicago since 2002, most recently as professor of biochemistry and molecular biology, director of the medical school's biomolecular nuclear magnetic resonance facility and a member of its Committee on Cancer Biology. In addition, he is a scientific co-director of the Chicago Biomedical Consortium, and a fellow of the American Association for the Advancement of Science.

His research has focused on the design and engineering of protein recognition interfaces.

Before coming to University of Chicago, Koide served on the faculty of the University of Rochester School of Medicine and Dentistry, including as director of the Biophysics and Structural Biology Graduate Program.

"Currently, eight of the top 10 selling pharmaceuticals are biologics, and numerous new biologic therapies are on the way," said Benjamin Neel, director of the Perlmutter Cancer Center.

"Unlike small molecule drug development, which is largely chemistry-based and often ill-suited for academic medical centers, many biologics have been developed within academia. Also, whereas less than five percent of small molecule drugs that enter clinical trials make it to market, about 20 percent of biologics actually become drugs."

MEMORIAL SLOAN KETTERING CANCER CENTER and **Cornell University** are opening a new $10 million **Center of Cancer Nanotechnology Excellence**.

The MSKCC-Cornell Center for Translation of Cancer Nanomedicines is funded with an $8.2 million grant from the NCI Alliance for Nanotechnology in Cancer and more than $1.9 million from MSKCC. The center—which will have one facility on the university's Ithaca campus and another at MSKCC in New York City—will focus on melanoma and malignant brain cancers.

The center is based on development and translation of Cornell dots, or C dots – silica-organic hybrid nanoparticles smaller than 10 nanometers in size designed to either adhere to and light up cancer cells or quickly leave the body. C dots are being tested in human clinical trials.

Work in the MSKCC-Cornell Center will include development of intraoperative optical detection tools to improve cancer localization, staging and treatment, as well as optimized therapeutic platforms that enhance delivery.

The center will also focus on four main areas: foundational science; multiplexed optical diagnostic applications in the surgical setting; particle radiotherapeutics; and assessment of particles in brain tumors for cancer therapy.

While the center will focus on pre-clinical research, it is partnering with two companies, one of which will focus on clinical applications. The yet-to-be-named startup will seek funding to help translate the center's research into more human clinical trials.

THE ONCOLOGY NURSING SOCIETY and **Clinical Care Options LLC** partnered to develop evidence-based resources, with the goal of creating a comprehensive self-study online reference and a fully searchable point-of-care decision support resource developed specifically for oncology nurses.

The program is led by Editors-in-Chief Dawn Camp-Sorrell and Rebecca Hawkins.

The inPractice technology platform contains original content, clinical databases and point-of-care reference look-ups. The platform is also available as mobile apps for Apple and Android phones and tablets.

SWOG and its charitable arm, The Hope Foundation, are providing $125,000 to five Department of Veterans Affairs medical centers.

Under the new VA Integration Support Program, each VA medical center will receive $25,000 in seed funding to help them enroll veterans in trials run by SWOG and other members of the NCI National Clinical Trials Network.

The awardees are: Central Arkansas Veterans Healthcare System; Cincinnati VA Medical Center; Durham VA Medical Center; VA Eastern Colorado Health Care System; and VA New York Harbor Healthcare System.

Drugs and Targets

Breakthrough Therapy Granted To Abemaciclib in Breast Cancer

FDA granted a Breakthrough Therapy designation to abemaciclib, a cyclin-dependent kinase 4 and 6 inhibitor, for patients with refractory hormone-receptor-positive advanced or metastatic breast cancer.

This designation is based on data from the breast cancer cohort expansion of a phase I trial, JPBA, sponsored by Eli Lilly & Co., which studied the efficacy and safety of abemaciclib in women with advanced or metastatic breast cancer.

Patients in this cohort had received a median of seven prior systemic treatments. These data were presented at the San Antonio Breast Cancer Symposium in 2014.

Lilly has an active clinical development program studying abemaciclib in breast cancer. MONARCH 1 is a phase II trial evaluating the use of abemaciclib as monotherapy in women with hormone-receptor-positive, human epidermal growth factor receptor 2-negative metastatic breast cancer.

In addition, Lilly is evaluating abemaciclib in two phase III clinical trials: MONARCH 2 to evaluate the combination of abemaciclib and fulvestrant in postmenopausal patients with HR+, HER2- advanced or metastatic breast cancer, and MONARCH 3 to evaluate the combination of abemaciclib and a nonsteroidal aromatase inhibitor in patients with HR+, HER2- locoregionally recurrent or metastatic breast cancer.

Merck and Bionomics Limited extended their strategic collaboration for the discovery and development of drug candidates for the treatment of chronic and neuropathic pain.

The latest agreement builds upon a collaboration signed in July 2013 focused on the discovery and development of novel, small molecule drug candidates for the treatment of chronic and neuropathic pain utilizing Bionomics' ionX and MultiCore drug discovery platforms.

Separately, Merck will also purchase approximately $9.4 million worth of Bionomics shares.

"I am delighted to welcome Merck & Co., as a shareholder of Bionomics. This investment provides further validation of our science," said Bionomics' CEO and managing director Deborah Rathjen.

Immunovia AB and the Knight Cancer Institute at Oregon Health & Science University formed a collaboration to confirm, validate and commercialize a blood test for the early diagnosis of pancreatic cancer.

The test, called IMMray PanCan-d, analyses a patient's immune system for early signs of disease. The collaboration will also enable researchers to explore biomarkers for a number of other cancer types.

Researchers at OHSU will help confirm the analytes used by the test by validating the findings on blood samples collected from consenting patients with pancreatic ductal adenocarcinomas.

"Our goal is to establish IMMray PanCan-d as a standard amongst pancreatologists and diabetes physicians worldwide for detecting pancreatic cancer in high-risk groups much earlier than is possible today," said Mats Grahn, CEO of Immunovia.

The collaboration will use patient samples collected through OHSU's Brenden-Colson Center for Pancreatic Care, together with matched controls, to run a retrospective study to verify, in a U.S. population, the findings of previous studies from Europe and China. The Brenden-Colson registry blood samples were collected at time of diagnosis, before, during and after treatment. The clinical validation study will cover about 600 samples with different stages of pancreatic cancer, matched controls as well as patients with chronic pancreatitis.

MD Anderson Cancer Center and Theraclone Sciences launched OncoResponse, an immuno-oncology antibody discovery company.

OncoResponse will use Theraclone's I-STAR immune repertoire screening technology to identify therapeutic antibodies against novel targets from immuno-oncology treated patients. MD Anderson will provide access to samples and physiologic, prognostic and genotypic data from patients who have responded well to cancer immunotherapies, along with oncology and translational medicine expertise.

The new company announced the closing of a $9.5 million Series A financing co-led by ARCH Venture Partners, Canaan Partners and MD Anderson. Rice University and Alexandria Real Estate Equities also participated.