THE CANCER LETTER

March 11, 2016 • www.cancerletter.com • Vol. 42 No. 10

CMS Experiment Targets Incentive To Use the Most Expensive Drug

By Paul Goldberg and Matthew Bin Han Ong

Is Average Sales Price plus 6 percent the right amount to pay doctors under the Medicare Part B program?

Would a smaller margin diminish what may be an incentive for doctors to prescribe the most expensive drugs on the market? With clinical performance being equal, or close enough to equal, is it not better for the doctor's wallet to bill 6 percent of the highest possible ASP available?

In a move that immediately set off an explosion in the cancer field, the Centers for Medicare and Medicaid Services announced a proposed rule to test new models to improve Part B payment for prescription drugs.

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Slamming the Door

Part VII: DePinho's Stock Tip Revisited

By Paul Goldberg

On May 25, 2012, I received an email from Len Zwelling:

Paul: It can't get worse than having our President pushing his own stock on TV. Len.

I clicked on the provided link to CNBC. What I saw was indeed difficult to process: a video of Ron DePinho, extolling the virtues of the stock of AVEO Pharmaceuticals Inc., a company he co-founded.

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In Brief

Esener to Lead Early Detection Research At OHSU Knight Cancer Institute

SADIK ESENER will direct the Center for Early Detection Research at **Oregon Health and Science University's Knight Cancer Institute**. Esener will also hold the Wendt Family Endowed Chair in Early Cancer Detection.

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CMS Experiment Seeks to Remove Incentives to Use The Most Expensive Drugs

(Continued from page 1)

According to CMS, the rule, proposed March 8, is designed to test different physician and patient incentives to accomplish two goals: "drive the prescribing of the most effective drugs, and test new payment approaches to reward positive patient outcomes."

Proponents say that the rule was conceived to save Medicare dollars by addressing rising drug costs, a trend to which physicians may contribute by prescribing more expensive drugs over equally effective—and cheaper—alternatives.

Critics characterized the CMS initiative as a "misguided," "perilous" and "perverse" policy that threatens viability of oncology practices—a policy change masquerading as an experiment.

"I understand that the way it works for the pharmaceutical industry is they can incentivize, garner market share by charging higher prices, because the doctors who make prescribing decisions make bigger margins on higher-priced drugs," said Peter Bach, director of the Center for Health Policy and Outcomes at Memorial Sloan Kettering Cancer Center. "All the evidence shows that, when doctors are faced with choices between treatments, and one provides a larger profit than the other, they tend to gravitate towards the more expensive, more profitable treatment."

ASCO described the CMS proposed rule as heavy-handed.

"CMS has released a proposed rule outlining a demonstration project that would modify drug reimbursement based on zip codes in certain regions of the U.S.," ASCO CEO Allen Lichter said in a statement. "ASCO believes that it is inappropriate for CMS to manipulate choice of treatment for cancer patients using heavy-handed reimbursement techniques.

"ASCO has long advocated for comprehensive payment reform to achieve high-quality, high-value care for every patient with cancer, and we hope the administration will reconsider the narrowly focused proposal today's announcement appears to pursue. Physicians did not create the problem of drug pricing and its solution should not be on their backs," Lichter said.

The proposed rule, which is open for public comment through May 9, uses a flat fee reimbursement model, which seeks to remove the incentive to pick more expensive treatments.

Though the experiment was made public this week, a summary appeared on the CMS website prior to the formal launch, apparently by mistake. This flawed rollout—more of a drip than a leak—allowed oncology groups to blast the experiment even before it was announced.

The objective of the system-wide experiment is to track utilization patterns without looking at patient benefit, critics said, interpreting the experiment as setting ASP add-ons based on ZIP codes. The study was apparently developed without direct input from cancer groups—and without their knowledge.

"Based on preliminary information that was released, we strongly urge you to withdraw any consideration of implementing this initiative," a sign-on letter from more than 60 groups of physicians and oncologists wrote in a letter to Andy Slavitt, CMS acting administrator.

"We are deeply concerned this risky, unproven experiment to Medicare Part B drug payments will jeopardize the health of millions of Medicare patients with cancer," the groups said in the letter dated March 7. "The proposed experiment to be implemented by the Center for Medicare & Medicaid Innovation appears simply to focus on Medicare drug spending rather than on patients and the quality of medical care they receive.

"Any CMMI experiment that forces these vulnerable Medicare patients to abandon treatments that are working and improving their quality of life is misguided and ill-conceived."

The letter is posted here.

This experiment reflects the reality of what CMS can and cannot do, critics say. The agency can try to manage costs by cutting the margins that go to oncologists. It can

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Subscription $420 per year worldwide. ISSN 0096-3917. Published 46 times a year by The Cancer Letter Inc.

also experiment with prescription patterns. What it cannot do is regulate drug prices directly.

The list of groups that signed a letter opposing the CMS study includes ASCO, the Community Oncology Alliance, the Association of Community Cancer Centers, the US Oncology Network, Cancer Support Community, CancerCare, and a large number of state oncology societies.

CMS did not respond to questions.

Bach likens the CMS experiment to the United Parcel Service's business model, which charges customers for moving boxes, regardless of the value of items inside those boxes.

"It's just a much better system in theory, and CMS aims to run an assessment to see if it works better for patients and spending. I think all the hullabaloo is about an announced experiment which is explicitly budget neutral, which means the same amount of money, and therefore, the profit margin is being delivered in a different way," Bach said to The Cancer Letter.

"I think all that's happening with CMS is they're trying to rationalize this so that the docs don't face a financial disincentive to use really inexpensive generic drugs, because right now, there's no margin in a drug that costs a few dollars, but there would be, if you're getting a flat fee for it.

"This is the direction I think we need to go in an experimental context—we'll know if something bad has happened as quickly as possible, and I think experimenting a payment reform is a lot better than just instituting it."

In a March 10 exchange with National Public Radio reporter Alison Kodjak, an ASCO spokesperson said, "ASCO did sign on to the letters, but may not have been entirely comfortable with some of the language."

"ASCO is currently assessing the full impact that the CMS proposal will have on the ability to provide patient-centered cancer care to all Medicare beneficiaries who need it, and will send detailed comments to CMS," ASCO's Lichter said in a statement. "The society will not yield in its push for a more rational drug reimbursement system and real payment reform."

The Design of the CMS Experiment

The proposed rule would test six different alternative approaches for reimbursing Part B drugs.

The agency's description of these six approaches follows:

• Improving incentives for best clinical care

Physicians often can choose among several drugs to treat a patient, and the current Medicare Part B drug payment methodology can penalize doctors for selecting lower-cost drugs, even when these drugs are as good or better for patients based on the evidence.

Today, Medicare Part B generally pays physicians and hospital outpatient departments the average sales price of a drug, plus a 6 percent add-on. The proposed model would test whether changing the add-on payment to 2.5 percent plus a flat fee payment of $16.80 per drug per day changes prescribing incentives and leads to improved quality and value. The proposed change to the add-on payment is budget neutral.

• Discounting or eliminating patient cost-sharing. Patients are often required to pay for a portion of their care through cost-sharing. This proposed test would decrease or eliminate cost sharing to improve beneficiaries' access and appropriate use of effective drugs.

• Feedback on prescribing patterns and online decision support tools. This proposed test would create evidence-based clinical decision support tools as a resource for providers and suppliers focused on safe and appropriate use for selected drugs and indications. Examples could include best practices in prescribing or information on a clinician's prescribing patterns relative to geographic and national trends.

• Indications-based pricing. This proposed test would vary the payment for a drug based on its clinical effectiveness for different indications. For example, a medication might be used to treat one condition with high levels of success but an unrelated condition with less effectiveness, or for a longer duration of time. The goal is to pay for what works for patients.

• Reference pricing. The proposed model would test the practice of setting a standard payment rate—a benchmark—for a group of therapeutically similar drug products.

• Risk-sharing agreements based on outcomes. This proposed test would allow CMS to enter into voluntary agreements with drug manufacturers to link patient outcomes with price adjustments.

Cancer Groups Object

The Community Oncology Alliance called the CMS initiative "misguided and a perilous" policy.

"It will only serve to accelerate the consolidation of cancer care into the more expensive hospital setting and undermine the physician-patient collaboration on the treatment of cancer," Ted Okon, executive director of the Community Oncology Alliance, said in a statement. "I thought we were at war on cancer, not cancer care."

The "perverse" experiment should be stopped, said COA President Bruce Gould.

"For the sake of all of our patients, we simply cannot let CMS proceed with the dangerous Medicare Part B Drug Payment Model, which is not a true 'model' in the CCMI legislative charter but simply another disguised cut to Medicare Part B reimbursement for cancer care," Gould said. "It is very revealing that CMS did not engage any patient and provider stakeholders in developing this perverse experiment, but is now seeking comment at the 11th hour."

In their sign-on letter objecting to the plan, cancer groups argue that there is no data that would suggest that payment changes would either improve the quality of care or reduce costs:

"In fact, a project by UnitedHealthcare implemented within community oncology practices designed to eliminate any 'incentive' proved the exact opposite to the CMS assumption. According to the study, 'eliminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy.' The spending on drugs increased by 179 percent."

The paper, "Changing Physician Incentives for Affordable, Quality Cancer Care: Results of an Episode Payment Model," was published in the Journal of Oncology Practice.

In the paper, by Lee Newcomer *et al.,* five medical groups that agreed to take part in the project were compared with a large national payer registry of fee-for-service patients with cancer. The objective was to examine the difference in cost before and after the initiation of the payment change. Between October 2009 and December 2012, the five groups treated 810 patients with breast, colon, and lung cancer using the episode payments.

Based on the registry, the predicted fee-for-service cost of the episodes cohort would have been $98.1 million. The actual cost was lower by almost a third: $64.8 million.

The cost of chemotherapy drugs would have been expected to be at $7.5 million, but was, in fact, just under $21 million.

"Modifying the current fee-for-service payment system for cancer therapy with feedback data and financial incentives that reward outcomes and cost efficiency resulted in a significant total cost reduction," the paper concludes. "Eliminating existing financial chemotherapy drug incentives paradoxically increased the use of chemotherapy."

The paper is posted here.

The margin CMS is using in an effort to either test or influence physicians' behavior is in reality lower than 6 percent, critics say.

In their letter, cancer groups said the add-on is closer to 2.3 percent.

"CMS must understand the actual Part B reimbursement rate before implementing fundamental changes that may have serious consequences for patients and providers," the letter states. "The ASP methodology currently includes a customary distributor prompt pay discount which reduces Part B reimbursement to approximately ASP plus 4 percent.

"Furthermore, Medicare applied the Budget Control Act of 2011 mandatory 2 percent sequester cuts to Part B drugs in such a way that the actual payment set by Medicare, after the prompt pay inclusion, is equivalent to approximately ASP plus 2.3 percent. It is imperative CMS understands and evaluates this current reimbursement rate and its outcome—especially as practices continue to close or consolidate with large health-systems, increasing costs for both patients and Medicare—and engage multiple stakeholders before implementing any initiative that would further reduce reimbursement rates."

Slamming the Door
Part VII - A Stock Recommendation

(Continued from page 1)

On the CNBC program "Closing Bell with Maria Bartiromo" May 18, DePinho brought up AVEO in the context of the upcoming meeting of the American Society of Clinical Oncology.

Here is a transcript of the appearance:

MARIA BARTIROMO: Are there companies out there, from an investment standpoint; for our audiences are obviously looking for money-making opportunities, trying to figure out how to capitalize on what's going on in this marriage of health care and technology and biotech. Are there companies out there that you think are most promising, and also what is going to come out of this ASCO meeting, you think?

RONALD DePINHO: Well, the companies in the biotech sector, you have to be very careful because you have to really understand which companies are driven by good management, that are driven by the kinds of scientific advances that I've mentioned, and there are a few of them out there. Historically, of course, Genentech was one of the prime examples of this, more recently a company…

MB: They were the first to come out with that targeted…

RD: Right. Targeted. So you think about Herceptin and so on, those are very important advances. And, in

fact, some of the most effective drugs have come out of the idea of using science to shepherd the cancer drug development.

A company that I was involved in founding—AVEO Pharmaceuticals, one of the more successful biotechs…

MB: That's A-V-E-O…

RD: That's correct… Has utilized, has exploited science-driven drug discovery, and it's about to announce, or has announced already publicly, and will present in detail at ASCO, a very effective drug that has a superior safety profile for renal cell cancer, a major unmet need.

So these are massive advances in our ability to really do something about a disease that has long been very refractory.

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I had to assure myself that I wasn't hallucinating.

I was watching a Texas state employee, whose conflicts of interest stemming from the ownership and management roles in a company have been recognized but not waived, offer investment advice that would benefit him personally.

Clearly, DePinho wasn't invited to the show to discuss AVEO. Rather, he was there as president of MD Anderson. AVEO was developing a drug called tivozanib, a tyrosine kinase inhibitor.

If approved—and renal cancer experts said that approval was not a sure thing—tivozanib at the time was vying to become drug No. 8 and the fifth drug in its class for the treatment of this relatively rare disease.

According to federal filings, DePinho and his family trust held 590,440 shares in AVEO. For three days preceding DePinho's appearance on CNBC, AVEO's stock price had been in a free-fall, trading at $11.28 per share just before DePinho went on camera.

The slide of per-share price, on a heavy trading volume, coincided with the announcement of top-line results from the company-sponsored clinical trial, which investors apparently interpreted as underwhelming.

However, following DePinho's appearance, the share price started to climb back up, trading at about $12.73 when the market closed on May 31, making the DePinho holdings worth about $7.5 million.

While there is no way to attribute this bump in the price of AVEO's stock to DePinho's on-camera salesmanship, the video clip provided a remarkable opportunity to watch him juggle his multiple roles and business interests.

I called Gilman a few times over those few days. It was all off-the-record, of course. He didn't see how DePinho could argue that AVEO was proposing a great pioneering therapy for renal cell carcinoma. It might have been a marginal improvement—if that.

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Many of the things DePinho said on that show were highly debatable.

I called several of my sources who understand renal cancer. All concurred that that DePinho's characterization of the AVEO drug as meeting a "major unmet need" was incorrect.

For one thing, the phrase echoes the term of trade "unmet medical need," which describes the FDA criteria for awarding a Fast Track designation, which allows the agency to work closer with the sponsor to get an important drug on the market.

I called AVEO, and a company official told me that they weren't applying for the

designation.

With eight drugs on the market, the renal cancer indication has more treatment options than most cancers.

In the pivotal trial, AVEO's tivozanib beat an older generation TKI, sorafenib, which is all that can be said.

Alas, tivozanib efficacy data—a delay in progression—had triggered a selloff. There was talk about a "survival deficit"—i.e., that patients who received the drug died sooner than patients who received a competing therapy.

I couldn't get anyone to discuss this in detail, so I decided to wait. The truth would come out soon enough, provided the company was serious about obtaining approval.

If the drug were indeed approved, the upside was uncertain. As the drug would be the eighth therapy and the fifth tyrosine kinase inhibitor used to treat a relatively rare cancer, it will never ring up the sales of a big indication drug like Avastin.

Since AVEO had no other drug in phase III trials, the company's future would be uncertain.

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By this time, I knew that this would be a long-running story, which would focus simultaneously on CPRIT and MD Anderson. I decided that I didn't want to find a new bioethicist to quote on every DePinho story.

Getting new commentators up to speed would simply eat up time. So I deputized two experts in ethics:

Art Caplan, director of NYU Langone's Division of Medical Ethics, and Sheldon Krimsky, professor of Urban and Environmental Policy and Planning at Tufts University, who writes books on medical ethics.

"This kind of media appearances are highly morally suspect, because you are conflating a number of different roles that have to be kept separate," Art said to me. "These include the role of a cancer researcher, the role as president of MD Anderson, the role as owner-investor in a company. This creates mixing of roles back-and-forth that cannot be mixed if you are to perform each of them in a responsible manner.

"Taking advantage of a platform to tout your company and its drugs means that you have to stay in that role and not move back and forth to other positions."

Krimsky said something similar:

"At a time when the U.S. Public Health Service and major medical journals are ratcheting up conflict of interest guidelines, it is morally unconscionable that the head of a leading public medical center should have an equity interest in a company whose financial interests can be affected by research at the center. A director donning two hats will always give the appearance of having a conflict of interest."

I circled back to Len Zwelling, too.

"It's just shocking to see him blatantly advance his own interests," Zwelling said. "Even Mendelsohn, who was amply compensated with ImClone stock for developing Erbitux and serving on the board, never acted as a pitchman for ImClone.

"He left it to Sam Waksal do that. And MD Anderson investigators continued to work with other EGFR receptors, including Iressa and Tarceva."

Then Zwelling reminded me about the conflict of interest rules that came out of the ImClone imbroglio, rules that were for some odd reason not applied to DePinho.

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I asked the company whether they engineered the interview.

"AVEO had nothing to do with Dr. DePinho getting booked on CNBC," said Rob Kloppenburg, the AVEO vice president of corporate communications. "We think the best thing to do would be to discuss the impetus for the interview with his representatives at MD Anderson."

Next, I contacted MD Anderson and emailed a series of questions for DePinho.

He called me within a few hours.

"I am a public official in a position of trust, and I should never comment on any of my personal holdings or give investment advice. It was a mistake for me to do so on the CNBC interview."

DePinho blamed the medium.

"It was live TV," he said. "It was a very fast-moving interview, which in the context of what Maria and I were talking beforehand, versus what we were talking on air, etc. It unfolded the way it did. And it will not happen again."

I asked a question about conflicts of interest, but received a non-answer:

"This is something that is very heavily managed in academic institutions," he said. "These are things that are very stringently examined at the level of systems and at the level of compliance, and these are things that have been examined in great detail with tremendous transparency."

Clearly, the UT System was not managing conflicts of interest of the president of the largest cancer center in the world.

Just saying "I am sorry" is rarely enough in matters that involve publicly traded securities.

Why did DePinho say what he did? How well did the company's only drug perform in clinical trials? Was the answer not communicated to DePinho, a member of the board of directors, and Chin, a member of the scientific advisory board? Answers to such questions don't make themselves immediately obvious, but they don't stay hidden for more than a few months.

The AVEO story had just begun to unfold.

For DePinho and Chin, the stakes were high: tivozanib was the closest thing they had to a successful therapy.

Nature itself had become an actor in the great Texas drama.

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Here is what I didn't know:

On May 7, 2012, eleven days before DePinho plugged AVEO stock, his wife Lynda Chin, the company's co-founder, traveled to the Boston area to take part in a meeting of the company's Scientific Advisory Board as it prepared to present clinical data to FDA.

The agenda of the May 7 meeting, which I would obtain later, consisted of three items, and "Discussion of TIVO-1," the phase III trial of the tivozanib, was one of these items.

The trial compared tivozanib with sorafenib in 517 patients with advanced renal cell carcinoma. Investors

who followed DePinho's advice would have seen their holdings erode. The company's development program for tivozanib collapsed as FDA noted that survival on the experimental arm was shorter than on the control arm.

"I did attend the May 7, 2012, AVEO Scientific Advisory Board meeting," Chin said in an email, responding to my questions. "Due to SAB confidentiality requirements, I am unable to disclose confidential or proprietary AVEO information; you may wish to contact AVEO for further information."

DePinho had said previously that he wasn't aware of FDA's views on the approvability of tivozanib when he appeared on CNBC.

This assertion would hold true if DePinho and Chin didn't talk about business. This is, in fact, what Chin said in response to my questions: "I did not discuss the SAB meeting in question with Dr. DePinho."

As an officer of the company, DePinho was required to report stock sales. Yet, according to disclosure forms filed by AVEO, he sold no stock during that period.

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A year later, on May 2, 2013, the FDA Oncologic Drugs Advisory Committee sunk tivozanib for the saddest of reasons: survival in the experimental arm of the sole randomized trial supporting the application was worse than survival in the control arm.

In July 2013, AVEO received a subpoena from the Securities and Exchange Commission, seeking documents and information on development of tivozanib. Nothing else is publicly known about the status of SEC inquiry.

A shareholders suit—a standard outcome of a bad day before ODAC—is currently on appeal. Court documents are posted here.

In March 2015, Judge Denise Casper of the U.S. District Court for the District of Massachusetts held that plaintiffs had failed to make a case for holding DePinho responsible for the statements he made in the interview.

"They do not… allege his basis for knowing about the FDA concerns

and do not allege later statements or evidence suggesting knowledge of same," the ruling states. "For these reasons, the Court concludes that sole statement by DePinho is insufficient for stating a claim against him, particularly in light of the absence of scienter."

Scienter is defined as an "embracing intent to deceive, manipulate or defraud."

The plaintiffs filed an amended complaint, but, in a ruling last November, the judge dismissed the case.

"The law requires that the inference of scienter 'must be more than merely plausible or reasonable it must be cogent and at least as compelling as any opposing inference of non-fraudulent intent,'" the judge ruled.

Next week: Part VIII – Conversations with DePinho

National Academy of Medicine Calls for Integrated FDA-CMS Pathway for Biomarker Tests

The National Academy of Medicine listed 10 goals for advancing the appropriate use of biomarker tests in precision medicine.

"How do we ensure patients have timely access to appropriate tests that may accurately direct targeted therapies, while at the same time protecting them from potential harm due to the adoption of poorly validated tests or inappropriately used tests?" the report asked, saying that broader implementation was being held back by a lack of consensus over evidentiary standards, inefficient and inconsistent regulatory and reimbursement approaches, the need for a framework for collecting patient data, and translating that data into improved patient outcomes.

The report concluded that "the full potential of precision medicine will not be realized without accurate, reliable, clinically useful, and appropriately implemented biomarker tests for molecularly targeted therapies."

"Biomarker tests for molecularly targeted therapies represent a crucial area of focus for developing methods that could later be applicable to other areas of precision medicine. The appropriate regulatory oversight of these tests is required to ensure that they are accurate, reliable, properly validated, and appropriately implemented in clinical practice.

"Moreover, common evidentiary standards for assessing the beneficial impact of biomarker-guided therapy selection on patient outcomes, as well as the effective collection and sharing of information related to those outcomes, are urgently needed to better inform clinical decision making."

The report, titled "Biomarker Tests for Molecularly Targeted Therapies: Key to Unlocking Precision Medicine," includes several recommendations, including the creation of a new integrated federal review pathway for regulatory, coverage, and reimbursement decisions for biomarker tests, as well as common clinical utility evidentiary standards.

The report's 10 goals for advancing the use of biomarker tests are:

• Establish common evidentiary standards of clinical utility—using evidence generated both within and outside the context of clinical trials—across all stakeholders.

• Establish a more coordinated and transparent federal process for regulatory and reimbursement decisions.

• Enhance communication to patients and providers about the performance characteristics and evidence for use of specific tests.

• Update and strengthen oversight and accreditation of laboratories providing these tests.

• Ensure ongoing assessment of the clinical utility of the tests.

• Ensure development and use of electronic health records and related biomedical informatics tools and assessment that support the effective clinical use of biomarker tests for molecularly targeted therapies.

• Develop and maintain a sustainable national database for these tests through biomedical informatics technology to promote rapid learning for the improvement of patient care.

• Promote equity in access to these tests and the expertise for effective use of test results in clinical decision making.

• Enhance specimen handling and documentation to ensure patient safety and the accuracy of biomarker test results.

• Improve the processes for developing and updating clinical practice guidelines for the effective use of these tests.

"We've just scratched the surface as far as science goes. But the rate of progress is incredible and it's accelerating almost daily which is exciting but represents a problem in its own right. It's virtually impossible for any individual or even any group to stay totally on top of developments in this rapidly evolving area," said Gary Lyman, a member of the committee that helped produce the academy's report.

"The ideal solution is what we call a rapid learning system. We need to develop strategies that include experts in informatics as well as the clinicians and laboratory scientists to find a way to identify, catalog and annotate," said Lyman, a breast cancer oncologist and professor at Fred Hutchinson Cancer Research Center and co-director of the Hutchinson Institute for Cancer Outcomes Research.

"This has to be automated if we're ever going to keep up with the rate of expansion of knowledge in this area. This isn't something that a single institution or even a group of institutions is likely to keep on top of—this has to be a concerted national effort, just like the proposed 'moonshot.' We're calling for this to be a national priority."

FDA should develop a patient- and provider-friendly standardized label for biomarker tests—including in vitro diagnostics and laboratory-developed tests—to facilitate the transparency of test performance characteristics, the report suggested, as well as the creation of a simple ranking system for the evidence supporting clinical validity and utility for each intended use, the report said.

The report also recommended that the Department of Health and Human Services establish updated laboratory accreditation standards, either through CMS's CLIA program or through another organization, saying that current CLIA standards are inadequate for current advanced biomarker tests performed with next-generation sequencing.

Other recommendations include the development and use of electronic health records; a task force to develop a national data repository for biomarker tests and molecularly targeted therapies; that licensing and specialty boards should ensure providers maintain competencies needed for effective use of the tests; and enhanced specimen handling and documentation to ensure patient safety and test results.

The academy's report also endorsed the idea that guideline-developing organizations, such as the Association for Molecular Pathology, the National Comprehensive Cancer Network, the American Society of Clinical Oncology among others, should expand interdisciplinary collaborations to develop integrated guidelines on the appropriate use of biomarker tests.

"Guidelines should be updated regularly and at intervals appropriate to advances in the field, widely disseminated, user-friendly, and developed with patient participation," the report said. "They should conform to standards articulated by authoritative groups, including the Institute of Medicine and Guidelines International Network."

The report also concludes that precision medicine may also have the unintended consequence of intensifying disparities in access to advanced health care. The report suggests that improved patient and provider education about precision medicine—as well as collaborations across health care settings—may help to reduce these disparities.

The 260-page report is available from the National Academies Press.

Companies, Health Systems Commit to Data Interoperability

Companies that provide 90 percent of electronic health records used by U.S. health care organizations have agreed to improve the flow of health information for consumers and health care providers, HHS officials said.

At the Health Information Management Systems Society conference Feb. 29, HHS Secretary Sylvia Burwell said the data companies pledged to implement the following changes:

• **Consumer Access:** This is defined as making it possible for consumers to get their electronic health information, direct it to any desired location, and learn how their information can be shared and used.

Many of the biggest health IT developers committed to using standardized application programming interfaces and a single shared standard for communicating with each other to enable user-friendly resources, like smartphone and tablet apps, can quickly be made available.

• **No Information Blocking:** Information sharing would be provided whenever permitted by law. The organizations agreed to refrain from blocking electronic health information, defined as knowingly and unreasonably interfering with information sharing.

The practice of information blocking was discussed in a recent report to Congress by the Office of the National Coordinator for Health IT.

• **Standards:** The organizations agreed to implement federally recognized, national interoperability standards, policies, guidance, and practices for electronic health information, and adopt best practices including those related to privacy and security.

Many of these groups are adopting ONC's Interoperability Standards Advisory—a coordinated catalog of existing and emerging standards and implementation specifications. This guidance is updated annually in order to keep pace with developments in the health IT industry. By identifying current best practices in standards, this advisory will assist healthcare providers to more easily collaborate with one another and share data across "interoperable" electronic health records.

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The top five largest private health systems in the U.S.—providing patient care in 46 states—and more than a dozen health care provider, hospital, technology and consumer advocacy groups joined the effort.

The organizations provided individual statements outlining how they are or will implement these shared principles in the months ahead.

"These commitments are a major step forward in our efforts to support a healthcare system that is better, smarter, and results in healthier people," Burwell said.

"Technology isn't just one leg of our strategy to build a better healthcare system for our nation, it supports the entire effort. We are working to unlock healthcare data and information so that providers are better informed and patients and families can access their healthcare information, making them empowered, active participants in their own care."

According to HHS, electronic health information currently flows in pockets of the healthcare system and business practices can inhibit data sharing. Even when electronic health information is shared, it can be underutilized and difficult to access due to hard-to-use technology or the use of different standards.

"The future of the nation's health delivery system is one where electronic health information is unlocked and shared securely, yet seamlessly, to put patients at the center of their own care," said Karen DeSalvo, national coordinator for health information technology.

"The broad agreement by leaders in health and health IT across the nation brings us much closer to our vision for a truly learning, connected health system."

Electronic health records need to be shared in a safe and secure way to advance research, The American Society of Clinical Oncology said in a statement.

"ASCO is proud to stand with members of the health care community in committing to advance interoperability among health information systems," ASCO President Julie Vose said in a statement. "Given our commitment in this area, we are pleased to uphold the three core principles outlined by HHS' in achieving interoperability. The commitment to developing standards for sharing information, preventing information blocking and enabling consumers to easily access and share their information completely aligns with ASCO's vision on this issue.

"On the clinical front, we have developed and are continuing to develop interoperability standards and treatment plans for sharing of cancer information. ASCO also has outlined steps Congress should take to advance the widespread interoperability of EHRs and prevent information blocking. In addition, we are

leading the development CancerLinQ, a cutting-edge HIT platform that will enable us to learn from each of the millions of individual patients living with cancer nationwide by unlocking, assembling and analyzing de-identified patient records.

"ASCO commends HHS and the Office of the National Coordinator for Health IT for their leadership in developing these principles and garnering support for them. We look forward to working with the EHR companies, health care systems and medical associations in carrying out these commitments."

The list of organizations making commitments follows:

Health IT developers: Aprima, Athenahealth, Allscripts, Cerner, CPSI, CureMD, Epic, GE Healthcare, Intel, McKesson, MedHost, Meditech, NextGen, Phillips, SureScripts, Optum, and Greenway Health.

Health care systems: Ascension Health, Carolinas Healthcare, Catholic Health Initiatives, Community Health Systems, Dignity Health, Geisinger Health System, Hospital Corporation of America, John Hopkins Medical, Intermountain Healthcare, Kaiser Permanente, LifePoint Health, Mountain States Health Alliance, Partners Healthcare, Tenet Healthcare, Trinity Health, and University of Utah Health Care.

Provider, technology, and consumer organizations: American Academy of Family Physicians, American College of Physicians, American Medical Association, American Medical Informatics Association, American Hospital Association, American Health Information Management Association, American Society of Clinical Oncology, Center for Medical Interoperability, College of Healthcare Informatics Management Executives, CommonWell, Health Information and Management Systems Society, Healthcare Leadership Council, Premier healthcare alliance, Sequoia Project, National Partnership for Women and Families, and National Rural Health Association.

Study: California Hospitals with Low Volumes of Surgeries Associated with Higher Risks

By Conor Hale

In California, nearly 75 percent of the state's hospitals performed only one or two surgeries when treating one of 11 selected cancer types in 2014, according to a report from the California Health Care Foundation.

The report linked the low hospital surgery volumes with higher rates of mortality and complications, while evaluating cancers of the bladder, brain, breast, colon, esophagus, liver, lung, pancreas, prostate, rectum and stomach.

"On average, patients who undergo surgeries for [these] cancers…at hospitals that perform relatively few of these surgeries—compared to hospitals that perform a high volume—are less likely to survive the surgery," the report said, adding that some patients of certain cancer types were also more likely to have longer stays in the hospital.

According to the report, less common surgeries—involving cancers of the bladder, esophagus, pancreas and stomach—were more likely to occur in hospitals that only perform one or two surgeries for that cancer. Surgeries for cancers of the breast, colon and prostate, however, were far less likely to occur at low-volume hospitals.

For example, of the 25,290 inpatient and outpatient breast cancer surgeries performed in California in 2014, 0.1 percent of the surgeries were performed at low-volume hospitals.

At the same time, 11 percent of stomach cancer surgeries were performed at low-volume hospitals. Stomach cancer surgeries at low-volume hospitals were associated with increased adverse outcomes such as higher mortality, failure to rescue and rates of transfer, according to the report, which found similar patterns each year from 2010 through 2014.

The 249 low-volume hospitals, out of 341 total, were mostly urban compared to rural, and split equally between hospitals that had more or fewer than 200 beds. Ninety-four percent of low-volume hospitals were nonteaching hospitals.

The report described how, in each cancer type, a majority of the surgeries performed at low-volume hospitals involved patients that lived within a 50-mile radius of a California hospital listed in the top 20 percent of surgeries by volume—i.e., 81 percent of prostate cancer patients undergoing surgery at

a hospital that only performed one or two of the procedures a year lived near a hospital that performed dozens to hundreds. Fifty-nine percent of all procedures in 2014 were performed at hospitals that fell within this top quintile.

The report included examples from other U.S. health systems that have set minimum annual volumes for cancer surgeries. In 2015, Dartmouth-Hitchcock Medical Center, the Johns Hopkins Hospital and Health System, and the University of Michigan Health System announced minimum numbers of procedures affecting up to 20 hospitals—including maintaining 40 surgeries per year in lung cancer, and 20 per year in pancreatic cancer.

The report also cited a volume requirement established by the New York State Department of Health in 2009 for Medicaid reimbursement for breast cancer surgeries: averaging 30 or more all-payer surgeries over a three-year period.

The report, "Safety in Numbers: Cancer Surgeries in California Hospitals," is available at the foundation's website.

Obituary

UNMC Scientist Michael Brattain Dies Unexpectedly at Age 68

Michael Brattain, University of Nebraska Medical Center Eppley Institute professor and associate director for basic research in the Fred & Pamela Buffett Cancer Center, died unexpectedly in his sleep March 5. He was 68.

"Mike was a brilliant scientist who had a prolific scientific career," said Kenneth Cowan, director of the Eppley Institute and the Buffett Cancer Center. "Mike's experience and input was extremely valuable to me in many areas within the Buffett Cancer Center.

"He made extensive contributions to the field of cancer research, and he will be remembered for the mentorship he provided to numerous graduate students and post-doctoral associates over the years. His sudden passing is a big loss for the Eppley Institute, the Buffett Cancer Center and the UNMC community. He will be greatly missed."

Brattain's laboratory studied the mechanisms for metastasis in colon cancer in order to find new targets for treatment. The research focused on the characterization of autocrine growth factors that played key roles in the regulation of cancer cell growth and dissemination including transforming growth factor alpha and transforming growth factor beta.

Brattain received his first grant award from NCI in 1978 and was continuously funded by the NCI since that time. In 2007, he was the recipient of a MERIT award from the NCI.

Since joining the Fred and Pamela Buffett Cancer Center in 2007, Brattain played a key role in reorganization of cancer center programs, core facilities and faculty recruitment, Cowan said. He also devoted significant time and effort to mentoring junior faculty and training graduate students and postdoctoral fellows.

"Mike had an uncanny ability to recognize strengths and talents in people before they recognized them in themselves, and he gave colleagues, trainees and staff the confidence to develop and capitalize on these talents," said Jenny Black, professor in the Eppley Institute and co-leader of the Gastrointestinal Cancer Program in the Buffett Cancer Center.

Brattain and Black were colleagues at Roswell Park Cancer Institute, and he was instrumental in recruiting Black to the Buffett Cancer Center from Roswell Park in 2011.

"Although he would never take any credit for his influence, many of us will be forever grateful for the tremendous impact he has had on our professional and personal lives," Black said.

Jenny Wang, an Eppley Institute associate professor, joined Brattain's lab in 1992 as a graduate student.

"He has been not only my mentor, but also like a father figure to me," Wang said. "He taught me many lessons on science and life. He has always been very supportive and encouraged me during difficult times. Without his help, I would not be who I am now. He was and will always be my role model, someone I look up to."

Brattain began his cancer research career at the University of Alabama, Birmingham, and held faculty positions at Baylor College of Medicine, Medical College of Ohio, University of Texas Health Science Center, San Antonio Cancer Institute and Roswell Park Cancer Institute before joining the Eppley Institute faculty in 2007. He received his undergraduate degree and Ph.D. in biochemistry from Rutgers University.

Prior to being recruited to UNMC, he served as the associate director for basic research at the San Antonio Cancer Institute and senior vice president for basic research and chair of pharmacology and experimental therapeutics at Roswell Park Cancer Institute.

During his eight years at UNMC, Brattain received the UNMC Distinguished Scientist Award in 2009, the UNMC Outstanding Mentor of Graduate Students Award in 2011, and the UNMC Research Leadership Award in 2015.

A celebration of Brattain's life and work will be held in the UNMC Eppley Science Hall Auditorium on March 25.

In Brief

Esener to Lead OHSU Center For Early Detection Research

(Continued from page 1)

Esener is a professor of nanoengineering and electrical and computer engineering at the Jacobs School of Engineering at the University of California San Diego. He has served as director and principal investigator of several centers of excellence in the areas of photonics and cancer nanotechnologies.

Most recently, he led the Cancer Nanotechnology Center of Excellence at UCSD's Moores Cancer Center to explore ways to use nanoscale devices to detect and target cancerous tumors.

Esener's recruitment comes just months after OHSU's successful completion of the $1 billion Knight Cancer Challenge from Nike co-founder Phil Knight and his wife, Penny. Among Esener's first responsibilities as director will be the recruitment of 20 to 30 scientists and their research teams to the OHSU Knight Cancer Institute's Center for Early Detection.

A gift by the Richard L. Wendt Family and the Wendt Family Foundation ensures ongoing support for Esener's role. It is the second such endowment created by the Wendt Family.

Esener has a breadth of experience in multiple scientific fields relevant to early cancer detection research, including micro and nanofabrication and optical, electrical and computer engineering. As a nanotechnology expert, engineer and computer scientist, he will bring an engineering systems-based approach to the role by integrating state-of-the-art technologies.

"I was drawn to OHSU because the leadership shares my dedication to effectively integrate disciplines such as cancer biology, oncology and medical engineering to focus on the challenge of cancer early detection," Esener said. "We are at a pivotal scientific moment as many new approaches such as fluid biopsies for detection and immunotherapies for treatment are emerging. My goal is to build a team that will leverage the pioneering work already underway at OHSU as well as the global collaborations it is developing to break ground in this area."

One of the first projects the program will undertake will be to develop liquid biopsy biochips that can serve as 'early warning' tools to gauge disease risk. Esener is expected to join OHSU in summer 2016.

JORGE LOPEZ JR. was named general counsel for **Memorial Sloan Kettering Cancer Center**, effective July 1.

Lopez is a partner at the law firm of Akin Gump Strauss Hauer & Feld LLP. He will succeed Roger Parker, who held the role since 1998 and earlier this year announced his plan to retire after 41 years of service to MSK.

Lopez has represented MSK on a variety of regulatory and legal matters for more than 20 years with healthcare and regulatory issues at both the federal and state level. He currently leads Akin Gump's healthcare practice, as well as its overall government regulatory group, overseeing the activities of more than 40 attorneys and other professionals.

Parker's career at MSK began in 1975 when he was recruited as director of nursing practice. He became chair of Nursing in 1978 and later spent 15 years as hospital administrator before being appointed as general counsel.

ARON PAREKH received a four-year, $790,000 Research Scholar Grant from the **American Cancer Society** to further his research into the mechanical and biological properties of cancer cells and the methods by which they leave the initial tumor and spread or metastasize to other parts of the body. Parekh is an assistant professor of otolaryngology at Vanderbilt University Medical Center.

Parekh said the response of cancer cells to tissue stiffness or rigidity in the tumor microenvironment plays a crucial role in driving these cells to leave the primary tumor site. He has been studying a molecule called Rho-associated kinase, or ROCK, which regulates the force that cells exert to determine how stiff something is.

ROCK exists in two forms and Parekh and colleagues recently discovered that the two forms work in different ways. To invade neighboring tissues, cancer cells must degrade the extracellular matrix of these tissues.

"We want to understand how tumor rigidity

regulates degradation through the forces that cancer cells use to sense how stiff the ECM is in both individual cancer cells and pairs of tumor cells. When we find cancer cells in pairs or triples and they're touching, which means they're interacting, there's often more degradation under them. What we're going to do then is measure forces between two tumor cells and see if the combined forces together make the cancer cells more invasive," Parekh said.

His collaborator on this grant is Julie Sterling, assistant professor of medicine in Clinical Pharmacology, Cancer Biology and Biomedical Engineering, who studies how cancer spreads to the bones.

ROBIN MJELLE received a $300,000 grant from the **Bonnie J. Addario Lung Cancer Foundation** and the **International Association for the Study of Lung Cancer**. Mjelle is a researcher at the Department of Cancer Research and Molecular Medicine at the Norwegian University of Science and Technology.

The ALCF-IASLC Joint Fellowship Award supports novel, innovative and translational research with the potential of having a high clinical impact on the early detection of lung cancer. Mjelle is working on the identification, characterization and validation of biomarkers for the early detection of lung cancer.

The prospective population-based HUNT2 and HUNT3 studies in Norway included 80,000 people with 190 clinical variables and blood samples collected during1996-1997 and 2006-2008. For 65,000 participants there is more than 15 years follow-up, where more than 500 participants were subsequently diagnosed with lung cancers, where diagnosis, diagnosis date and date of death of all subjects are known. Using this cohort, Mjelle and colleagues plan to develop a risk-prediction tool that will help the development of a serum poly-marker kit.

WILLIAM GRADY was awarded a $180,000 grant from the **DeGregorio Family Foundation for Gastric and Esophageal Cancer Research** and the **Price Family Foundation** for a two-year project to develop methods to identify people at the highest risk for esophageal adenocarcinoma. Grady is a clinical researcher and cancer geneticist at Fred Hutchinson Cancer Research Center.

The risk of adenocarcinoma is tenfold higher for individuals with Barrett's esophagus, a change in the esophageal lining that occurs in people who have chronic heartburn and gastroesophageal reflux. Cancer in patients with Barrett's esophagus can be prevented or treated successfully if caught early by endoscopy. Grady's team aims to find a simple way to spot those patients who should get frequent endoscopies, while sparing others unnecessary discomfort.

He and research partner Georg Luebeck, a computational biologist and member of the Public Health Sciences Division at Fred Hutch, plan to achieve this with a test that can accurately determine the biological age of esophageal tissue, which results from biochemical wear and tear, and detecting the processes of DNA methylation.

BAYLOR COLLEGE OF MEDICINE and **Baylor Scott & White Health** have entered into an agreement to expand biomedical research in North and Central Texas.

The largest not-for-profit health care system in Texas, Baylor Scott & White Health was born from the 2013 merger of Baylor Health Care System and Scott & White Healthcare.

A search committee is now being established to recruit a chief scientific officer, who will oversee the collaborative effort and serve as a section chief in the Baylor College of Medicine Department of Medicine. The leader will report to Adam Kuspa, Baylor College of Medicine senior vice president, dean of research and dean of the Graduate School of Biomedical Sciences, and will work closely with the Baylor Scott & White Research Institute.

The collaboration will be governed by a Research Oversight Council, composed of eight members, equally representing both institutions. New faculty will be hired in both Dallas and Temple as Baylor College of Medicine faculty and current faculty will transition to Baylor faculty appointments over time.

TUFTS MEDICAL CENTER and **New England Cancer Specialists** formed a clinical affiliation to expand patients' access to care, clinical trials, and survivorship resources.

NECS is the largest provider of cancer services in Maine, with nearly 45,000 patient visits in 2015 at locations in Scarborough, Brunswick and Kennebunk.

Through the affiliation agreement, Tufts MC will be NECS's preferred academic medical center when patients need complex treatments such as bone marrow transplants, second opinions, or access to innovative clinical trials. Together, they plan to promote an Oncology Medical Home program, collaborate on virtual tumor boards, and partner on precision medicine and the application of immunotherapy.

UC SAN FRANCISCO and **Berkeley Lights Inc**. formed a collaboration that gives UCSF researchers access to Berkeley Lights' opto-nanofluidic biosystems, including single-cell genomic profiling of pre-annotated tissue samples, the development of precision diagnostics, and point-of-care therapies.

Through the collaboration, UCSF researchers will study various cancer types to better understand the characterization and functionality of cell types in the progression of the disease and responsiveness to treatments.

"Single-cell genomics is a very exciting emerging field which will likely have considerable impact in the clinic," said Alan Ashworth, president of the UCSF Helen Diller Family Comprehensive Cancer Center. "The BLI technology uses a unique, automated system that allows us to scale rapidly our research to understand how the state of individual cells and cell types correlates with disease status, progression, and response to therapy. Exploiting this innovative technology, we will identify and develop precision diagnostics and therapies which we aim to translate into clinical practice."

Drugs and Targets

Xalkori Approved in Metastatic Non-Small Cell Lung Cancer

FDA approved Xalkori (crizotinib) to treat people with metastatic non-small cell lung cancer whose tumors have an ROS-1 gene alteration. Xalkori, sponsored by Pfizer, is the first and only FDA approved treatment for patients with ROS-1 positive NSCLC. FDA previously granted the Xalkori expanded use application breakthrough therapy designation and priority review status.

ROS-1 gene alterations are present in approximately 1 percent of patients with NSCLC. The overall patient and disease characteristics of NSCLC with ROS-1 gene alterations appear similar to NSCLC with anaplastic lymphoma kinase gene alterations, for which crizotinib use was previously approved. Xalkori was approved to treat certain patients with late-stage NSCLC that expresses an abnormal ALK gene in 2011.

"Lung cancer is difficult to treat, in part, because patients have different mutations, some of which are rare," said Richard Pazdur, director of the Office of Hematology and Oncology Products in the FDA's Center for Drug Evaluation and Research. "The expanded use of Xalkori will provide a valuable treatment option for patients with the rare and difficult to treat ROS-1 gene mutation by giving health care practitioners a more personalized way of targeting ROS-1 positive NSCLC."

The safety and efficacy of Xalkori for the treatment of patients with ROS-1 positive tumors were evaluated in a multi-center, single-arm study of 50 patients with ROS-1 positive metastatic NSCLC. Results showed 66 percent of participants experienced a complete or partial shrinkage of their NSCLC tumors, an effect that lasted a median of 18.3 months. The safety results of this study were generally consistent with the safety profile of Xalkori evaluated in 1,669 patients with ALK-positive metastatic NSCLC.

FDA approved the American College of Radiology's alternative standard request to allow mammography facilities to use the new Digital Mammography Quality Control Manual and Digital Mammography QC Phantom in routine QC of digital equipment. The new manual and phantom will aid in ensuring uniformity of QC testing, the ACR said.

The FDA alternative standard specifies that the new manual may only be used for full-field digital

mammography systems without advanced imaging capabilities, such as tomosynthesis or contrast enhancement.

"The new ACR manual will promote uniformity of testing since it will allow facilities with applicable systems to follow one manual instead of the dozens of different manuals that are mandated for the varying manufacturers and models of digital mammography equipment," said Eric Berns, lead author and chair of the ACR Subcommittee on Mammography Quality Assurance. "The new manual focuses on tests that are clinically relevant for high-quality imaging and the structure for a thorough and complete quality control program," he added.

The manual is currently undergoing preparation for publication and should be available this spring. ACR-accredited mammography facilities (and those applying for accreditation) will be invited to download the PDF manual at no charge. Medical physicists associated with ACR-accredited facilities will also be allowed to download the manual at no charge.

"This new manual provides simple, user-friendly procedures for technologists and medical physicists to help them maintain this quality of imaging," said Brett Parkinson, chair of the ACR Committee on Mammography Accreditation. He noted that the ACR manual "also contains two optional procedures for radiologists to enable them to self-check system image quality and provide image quality feedback to technologists."

Regulatory authorities in six countries have granted 10 sales authorizations for Yondelis.

Five of those authorizations are for Yondelis (trabectedin) in combination with Caelyx (pegylated liposomal doxorubicin) for treating relapsed platinum-sensitive ovarian cancer, in Bangladesh, Costa Rica, Kuwait, Moldavia and Saudi Arabia

The other five authorizations are for Yondelis for soft tissue sarcoma, in Bangladesh, Brunei, Kuwait, Moldavia and Saudi Arabia

As a result, Yondelis is now approved in nearly 80 countries, 31 of which are in the European Economic Area. The European Commission approved Yondelis for soft tissue sarcoma in 2007, and at the end of 2009 they approved the sale of this drug in combination with Caelyx for relapsed platinum-sensitive ovarian cancer.

In 2015, the FDA gave Janssen Products LP marketing approval for Yondelis for the treatment of patients with unresectable or metastatic liposarcoma or leiomyosarcoma; and the drug was also approved by the Japanese Minister of Health, Labor and Welfare to Taiho Pharmaceutical Co., Ltd. for the treatment of patients with soft tissue sarcoma.

Yondelis also has orphan drug status for soft tissue sarcoma and ovarian cancer in the European Union, the United States, and Switzerland, and for soft tissue sarcoma in Japan and South Korea.

According to the licensing agreement between Janssen Products and PharmaMar, PharmaMar has the rights to sell Yondelis in Europe, including Eastern Europe, while Janssen Products has the rights to sell the drug everywhere else except Japan, where PharmaMar has granted a license to Taiho Pharmaceutical Co., Ltd.

Yondelis is a novel, multimodal, synthetically produced antitumor agent, originally derived from the sea squirt, Ecteinascidia turbinata. The drug exerts its activity by targeting the transcriptional machinery and impairing DNA repair.

The China Food and Drug Administration approved the CINtec PLUS Cytology test, developed by Roche, for identifying women with cervical pre-cancer.

A multi-center study of five participating hospitals throughout China revealed greater overall performance of combined sensitivity and specificity of the CINtec PLUS Cytology test in determining which women are at higher risk of developing cervical cancer when compared to conventional screening methods like Pap cytology. This is consistent with previously published data and supported the approval of the test by the CFDA.

The CINtec PLUS Cytology test was developed to detect two biomarkers associated with persistent HPV infections that may lead to cancer, distinguishing them from those that are likely to resolve on their own. The test is also available in Europe, Asia, Latin America and Canada.

Veritas Genetics introduced Veritas myGenome, a whole genome sequencing platform for less than $1,000, including interpretation and genetic counseling.

The platform includes a digital report and app to interact with results, on-demand additional genetic counseling via video conferencing, and lifestyle-relevant genetic information that can be shared with non-clinical service providers such as fitness coaches and nutritionists. It also integrates other omics datasets.