News Analysis

Biden's Moonshot Goals are Flexible Enough to be Realistic

By Matthew Bin Han Ong, Katie McKinney and Laura Brawley

After a year of trying to understand the biology and politics of cancer, Vice President Joe Biden admits that he has a stronger grasp on the nuts and bolts of Washington than the evolutionary mysteries known collectively as cancer. Hosting the National Cancer Moonshot Summit at Howard University

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Biden Announces FDA Center of Excellence

By Matthew Bin Han Ong

Vice President Joe Biden announced the formation of the FDA Oncology Center of Excellence, which is intended to consolidate the agency’s cancer portfolio and streamline regulatory pathways for cancer-related drugs, biologics, and devices.

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Conversation with The Cancer Letter

Pazdur Named Acting Director of FDA’s New Cancer Center

Richard Pazdur, currently the director of the FDA Office of Hematology and Oncology Products, will serve as acting director of the newly formed FDA Oncology Center of Excellence.

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Moonshot Goals are Flexible Enough to be Realistic
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on June 29, Biden delivered a wide-ranging speech, even as his main initiatives remain what they have been from the start of his cancer odyssey:

1) Biden announced a reorganization of FDA, potentially imposing a single strategic vision on what is now a disparate portfolio that splits oncology-related devices and diagnostics from therapeutics, and places a divide between drugs and biologics. See the story on page 1 and a conversation with Richard Pazdur, the newly appointed acting director of the Oncology Center of Excellence.

2) From the beginning, Biden addressed the genesis of the Tower of Babel-like inability of bioinformatics systems to exchange data. (The problem was inadvertently created by the Obama Administration when it mandated a switch to electronic medical records in the 2009 stimulus bill.) At the summit—after months of roundtables and cajoling stakeholders to collaborate—he endorsed several initiatives, including a partnership between NCI and Foundation Medicine, a new, interoperable NCI clinical trials interface, and the Oncology Precision Network, a consortium of five health systems that use Syapse, an IT platform that enables data sharing.

Cancer, arguably more than any other disease, inspires saber-rattling rhetoric, and imagery of war is used interchangeably with imagery of space travel. However, unlike Andrew von Eschenbach’s unsuccessful plan to “eliminate suffering and death due to cancer by 2015,” the Biden plan seeks to make 10 years’ worth of progress in the next five years.

If the Biden moonshot consolidates FDA’s oncology portfolio—a finite task—and makes fundamental fixes in bioinformatics and the culture of research, that would be a step forward.

“The impediment isn’t the lack of the gray matter genius and ingenuity in terms of new drugs, new treatments, etc.,” Biden said at the summit. “It’s all this stuff that gets in the way.”

The text of Biden’s speech appears on page 8.

In the past, when NCI’s advocates attempted to raise additional funds for cancer, NIH officials insisted that other areas of research get corresponding increases. By setting cancer apart from other diseases, Biden’s moonshot may pave the way for targeted funding boosts for cancer research.

Indeed, the bulk of the moonshot funds—$750 million—are slated to come in fiscal year 2017, after the Obama administration.

Altogether, the White House announced 40 new developments related to the moonshot. During Biden’s daylong summit at Howard University, many entities across the U.S. held smaller, regional summits.

The day after the summit, Biden visited the Case Comprehensive Cancer Center because of a citywide proposal to develop science-driven efforts to reduce the excessive rates of smoking in Cleveland and to increase HPV vaccination rates. The effort includes the University Hospitals Seidman Cancer Center, the Cleveland Clinic, Case Western Reserve University and researchers at MetroHealth.

“Vice President Biden advances the notion that it is time to stop cancer as we know it,” Stan Gerson, director of Case Comprehensive Cancer Center and UH Seidman Cancer Center, said in his introduction of Biden. “I was honored to participate in this amazing day. There was passion, urgency and alignment in the rooms and break out sessions. It was truly a remarkable experience. For the first time, I had the sense that many barriers will fall, and that priorities will be reestablished.”

All the obvious limitations notwithstanding, Biden appears to bet that the moonshot will create the atmosphere of openness, making Congress, government agencies and non-profits increase funding for cancer research.

An example: Gary Reedy, CEO of the American Cancer Society didn’t come to the June 29 summit empty handed. ACS said it plans to increase its annual research spending $240 million by 2021. The society spends about $100 million a year in new grants to academic

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Biden Announces FDA Center of Excellence
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Richard Pazdur, currently the director of the Office of Hematology and Oncology Products, will serve as acting director of the agency’s new cancer center.

Biden’s June 29 announcement at the National Cancer Moonshot Summit in Washington, D.C. follows months of lobbying by oncology professional societies, advocacy and patient groups.

These groups are now watching to make sure that OCE would have a concrete reporting structure to bring all cancer-related products—now regulated separately in three centers in different divisions—under one roof.

In the past, the agency and the Obama administration said that the new center could be “virtual,” i.e. that desks may not need to be moved. The V-word didn’t figure in either Biden or FDA’s announcements June 29 (The Cancer Letter, May 6).

As acting director, Pazdur now has some authority to formalize who and what goes where in a potential agency-wide reshuffle of oncology resources.

Pazdur is expected to coordinate with the agency’s three centers—the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research and the Center for Devices and Radiological Health—and report to FDA leadership on the structure of the program.

“Center directors from CDER, CBER, and CDRH will work alongside Dr. Pazdur in his role as OCE acting director to formalize an innovative, yet seamless cross-center regulatory approach to enhance the coordination of clinical review across oncology-related drugs, biologics and medical devices,” FDA Commissioner Robert Califf said in a statement June 29.

The White House moonshot directive for an integrated cancer center comes with $75 million—which advocates say is insufficient—in new mandatory funds for FDA in the 2017 fiscal year (The Cancer Letter, Feb. 12).

“We will be asking for appropriations for this, obviously,” Pazdur said to reporters at the National Cancer Moonshot Summit at Howard University June 29. “I think the structure has to dictate what our funding requirements will be and that’s yet to be defined, and how much is going to be borrowed from other centers, etc., as we establish this office.”

An acting director will be selected to replace Pazdur at the Office of Hematology and Oncology Products.

Despite its title, the Oncology Center of Excellence is a program, not a center equivalent to CDER, CBER, or CDRH.

“We don’t have a deadline, and what I’m more interested in doing is making sure that everybody’s voice is heard,” Pazdur said. “One of the first things that I want to do at this point really is to sit down with a review staff.

“No one likes change. My late wife used to say that the only person that loves change is a baby with a wet diaper. Unless you have everybody on board with this, it can’t work in an optimal fashion.”

In earlier months, the proposed consolidation appeared to run into internal opposition at FDA, particularly in units that stand to lose authority, staff and budget in the potential reorganization.

In a statement to The Cancer Letter at the time, FDA leadership said that it would establish the staffing and structure for a “virtual” cancer center in fiscal 2017, triggering an outcry from cancer groups that demanded speedier decision-making (The Cancer Letter, May 6).

In one of his chatty asides at the summit June 29, Biden said he exerted pressure over a federal agency that was dragging its feet on appointing a “new director” until the end of the year.

“I won’t mention the particular agency, but we’ve had, one of the agencies in the federal government said they’re going to get a new director, and said ‘We’ll have it by the end of 2016,’” Biden said.

“I called the head of that department in and said, ‘[End of] 2016? It is now June. If you can’t get that director in the next four months, tell me, we’ll go find someone else who can find them.’

“It’s bizarre. Some of your actions are like that: we can do it later.”

At 8:10 a.m., a few hours before Biden spoke at the moonshot summit, FDA announced Pazdur as acting director of the OCE.

“After a competitive internal search, I can think of no one more qualified to shepherd the agency into a new era of regulation over oncology products than the FDA’s own Dr. Richard Pazdur, who has led the FDA for nearly 20 years in reshaping and modernizing the review of cancer treatments,” Califf said in the statement June 29.

research institutions and another $15 to $20 million on intramural research.

“It aligns very nicely with the moonshot,” Reedy said to The Cancer Letter. “It’s what all of us need to do. If we collaborate, we will get there quicker.”
“Dr. Pazdur is the person the FDA needs to get the OCE up and running, because of his in-depth understanding of the inner workings of the FDA, his deep expertise in treating this complex disease and his ability to move the agency forward in this complicated task.

“We look forward to Dr. Pazdur’s and the center directors’ work to lead the FDA in rapidly implementing the cross-cutting efforts of the OCE in this initial phase.”

Cancer Groups: Pazdur is the “Perfect Pick”

Pazdur is the “perfect pick” to lead the OCE, said Ellen Sigal, chair and founder of Friends of Cancer Research, the organization that led the advocacy effort to create the program.

“Working with the Vice President on this initiative has been inspiring,” Sigal said to The Cancer Letter. “To see him help lead the moonshot, especially the creation of the Center of Excellence, proves that even in a gridlocked Washington, many are willing to put differences aside for the benefit of patients.

“By naming Dr. Pazdur, one of our country’s most dynamic scientific leaders, to head the center, the vice president and the FDA has signaled to the community how important this is to the broader moonshot goal of curing cancer.”

On June 6, 28 oncology professional societies and advocacy organizations sent a letter to FDA Commissioner Robert Califf, describing the organizational structure they’d like to see in the proposed center (The Cancer Letter, June 10).

FDA should make Pazdur the permanent director of the OCE, not just acting director, the American Association for Cancer Research said in a statement.

“It was especially gratifying to hear that the FDA has selected Dr. Rick Pazdur to lead this important new Oncology Center of Excellence, and we look forward to the FDA designating him as its permanent Director very soon,” AACR CEO Margaret Foti said. “Dr. Pazdur has worked tirelessly to speed the availability of therapies for cancer patients, especially when the drugs are the first available treatments or have advantages over existing therapies.

“In addition, Dr. Pazdur has worked for years to build collaborative partnerships with academia, industry, other government agencies, scientific societies, and patient advocacy organizations to improve the pace and quality of new cancer drugs reaching patients. He also has embraced regulatory science to truly inform and improve the way in which new cancer medicines can be evaluated for their safety and efficacy.”

On an annual basis, approximately 30 percent of all new drugs approved by FDA are oncology products. Pazdur is widely credited for reforming and creating the existing processes for regulating anticancer drugs.

Pazdur’s office has approved many novel treatments that have extended the lives of patients and markedly improved their quality of life, said Daniel Hayes, president of the American Society of Clinical Oncology.

“ASCO commends FDA Commissioner Dr. Robert Califf for his selection of Dr. Richard Pazdur to lead the agency’s new Oncology Center of Excellence,” Hayes said in a statement. “In his nearly 20 years with the FDA, Dr. Pazdur has worked innovatively to dramatically reduce the amount of time to review new products and increase the number of safe and effective oncology products available to cancer patients. He consistently demonstrates the necessary leadership and commitment to improving cancer care for directing this new center to carry out its mission.

“ASCO applauds the remarkable success of the FDA in regulating oncology products. However, we believe a more coordinated approach will further streamline and organize evaluation of oncology products—both therapeutic and diagnostic. We have been supportive of calls for development of Centers of Excellence within the agency that globally review all aspects of a single disease, and we are pleased that Dr. Pazdur has been appointed to direct the oncology center.

“The oncology center is coming at a crucial time in response to the need to coordinate review of drugs, diagnostic tests, and other types of devices,” Hayes said. “This large-scale agency reorganization will require a great deal of vision and planning to ensure that the new center fully achieves its goals of bringing safe and effective oncology products to market more efficiently. There is no better person to lead this effort than Dr. Pazdur.

“ASCO is very supportive of the new FDA Oncology Center of Excellence and the selection of Dr. Pazdur to lead it. We are ready to work with Dr. Pazdur and the FDA as this new center is formed and works to meet the needs of people living with cancer.”

Pazdur is a “natural fit” for the OCE, the American Cancer Society Cancer Action Network said.

“We congratulate Dr. Pazdur on his appointment,” ACS CAN said in a statement said to The Cancer Letter. “As the head of OHOP at CDER, he has provided strong leadership and a dedication to advancing regulatory science and innovative review pathways within FDA, while maintaining a focus on the needs of cancer patients.
"He is a natural fit to lead the newly formed Oncology Center of Excellence and we look forward to working with him as the new Center is created.

Pazdur’s appointment will amplify FDA’s work on pediatric oncology, said Nancy Goodman, executive director and founder of Kids v Cancer.

“It’s just terrific for children with cancer that Dr. Pazdur is appointed acting director of the cancer center,” Goodman said to The Cancer Letter. “The next step will be to establish the center as an integrated cohesive whole that can quickly and fully respond to scientific advances.”

The OCE is the first step to ensuring the rapid and timely approval of safe and effective treatments, said AACR President Nancy Davidson, director of the University of Pittsburgh Cancer Institute.

“It is important for the FDA to be structured and managed in a way that enables it to respond in a much more coordinated way to the needs of cancer patients, the interests and goals of cancer drug and test developers and manufacturers, and the rapidly changing scientific environment, as we have seen in the areas of companion diagnostics and next-generation sequencing (NGS) tests,” Davidson said. “Therefore, we believe that this is a prudent move by the FDA to establish this new Oncology Center of Excellence.”

Conversation with The Cancer Letter
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The exact structure, budget and staffing for the program will be determined in an ongoing process, Pazdur said to The Cancer Letter.

“Because I will be working to develop the structure of the OCE with input across all centers, it would be premature to speculate about what the ultimate structure of the OCE will be,” Pazdur said. “The framework of the OCE will evolve over time, so as not to disrupt the ongoing work in each center.”

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

Matthew Ong: Does this announcement mean that the Oncology Center of Excellence will no longer be virtual? Will the OCE be real—i.e., will it actually have authority to make meaningful decisions?

Richard Pazdur: I think the question people are asking is what the structure of OCE will be and how other staff at FDA will be involved—and that is exactly what my role will be as the acting director: to help chart a course for developing and executing an integrated program for oncology product clinical review, and for providing clinical advice and guidance to the commissioner, center directors and other executives on FDA oncologic-related programs and issues.

But because I will be working to develop the structure of the OCE with input across all centers, it would be premature to speculate about what the ultimate structure of the OCE will be. The framework of the OCE will evolve over time, so as not to disrupt the ongoing work in each center.

Establishing a center of excellence in a disease-management area like cancer across drugs, biologics and devices requires a thoughtful approach and is an ongoing process.

I look forward to guiding the agency through this initial phase in support of the National Cancer Moonshot Initiative, and our objective is to move as quickly as possible toward establishing the OCE, while ensuring the work across centers continues without disruption.

MO: What was your vision for FDA regulation of oncology products when you first joined the agency in 1999? How does the OCE fulfill that vision in creating a seamless and effective regulatory pathway for oncology products?

RP: I’ve always had a vision to enhance collaboration and focus our work in oncology here at the FDA in disease-specific teams. That was one of the first things I did when I became the director of what was then the Division of Oncology Products in CDER, and I think the OCE is a continuation of that across medical products.

This OCE builds upon the collaborative work that the oncology team at FDA has been working toward. For example, one model that has worked well in the past is holding cross-center monthly meetings to discuss key oncology issues, collaborative workshops and programs, and working together on research and scientific publications.

I am also honored to help facilitate engagement externally with oncology stakeholders, including patient-focused advocacy groups, professional associations, industry, academia, sister agencies such as the National Institutes of Health and international regulatory agencies. The FDA has incredibly strong partnerships in oncology that we look forward to building upon through the OCE.

Anyone who knows me knows that two things at the heart of what I try to bring to the table are the patient voice, and fostering innovation.
At the FDA, the patient voice is an integral part of our regulatory decision-making, based on professional responsibility and personal experience. This will continue to be valued in the work of the OCE across oncology-related products.

At FDA we support innovation and believe that multiple treatment and diagnostic options are in the best interest of patients. I look forward to continuing to support the agency’s mission in this regard.

**MO:** Now that you have the authority to chart the course with the FDA leadership and other centers, what will be your first order of business?

**RP:** The very first thing I plan to do in my role as acting director of the OCE is meet individually with those involved in oncology medical product development and review across centers to hear their ideas for the OCE, and how we can work together to enhance our oncology efforts across the agency. I want to understand where they believe we can make the biggest impact.

The only way to build a successful OCE is collaboration, by taking the best ideas from across centers, industry, and the patient and physician communities to help shape the OCE from the ground up.

I look forward to meeting the center directors from CDER, CBER and CDRH to formalize an innovative, yet seamless cross-center regulatory approach to enhance the coordination of clinical review across oncology-related drugs, biologics and medical devices.

**MO:** I know that the details have not been hashed out, but generally, can patients, industry and other stakeholders expect drugs, devices and biologics—related to cancer or that pose oncologic risks—to eventually become subject to review, in one way or another, under OCE?

**RP:** You’re right that we are still working through the details, but what we do know is that the OCE will leverage the combined skills of regulatory scientists and reviewers with expertise in drugs, biologics, and devices, including diagnostics.

This center of excellence will help expedite the development of oncology-related medical products and support an integrated approach in:

- Evaluating drugs, biologics, and devices for the prevention, screening, diagnosis, and treatment of cancer;
- Modernizing existing business processes and enhancing IT systems to enable an outcome-focused operating model and establish a regular cadence of delivering value and measurable outcomes;
- Supporting the continued development of companion diagnostic tests, and the use of combinations of drugs, biologics and devices to treat cancer; and
- Developing and promoting the use of methods created through the science of precision medicine.

More details on approval processes will be shared once the structure is established. I’m really looking forward to working closely with others here at the FDA to bring this vision to life.

**MO:** Since you are on detail for the OCE, how will the Office of Hematology and Oncology Products be managed?

**RP:** An acting director of the Office of Hematology and Oncology Products will be appointed to take over my previous responsibilities. More details about that transition will be shared once that selection has been made.

**MO:** Is there a tentative timeline for when FDA expects to launch a full-fledged OCE?

**RP:** We are working expeditiously toward our goal of establishing the OCE as quickly as possible. For example, we have already held listening sessions and heard valuable input from patient and physician communities, as well as industry and internal audiences.

The reason for my appointment as acting director is to accelerate the integration of various disciplines involved in the clinical review of oncology products at the FDA.

**MO:** Did I miss anything?

**RP:** I want to thank everyone who has supported me and the FDA in our work to get the OCE up and running. As Vice President Biden said at the Cancer Moonshot Summit this week, we have a lot of work ahead of us, but we have a lot of people working with us to change cancer as we know it.

At the FDA, we are dedicated to serving the needs of the patient and health care communities and we will get this right.

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http://www.cancerletter.com
Biden: What I Learned About Cancer

A transcript of Biden’s speech at the National Cancer Moonshot Summit at Howard University June 29 follows:

What changes do we have to make, if any, in this fight?
All across the country, all under a national charge from the White House to do something big but very possible: Make a decade’s worth of progress in the next five years.

When the moonshot was first announced, some said, “Well, Biden’s being naïve, ending cancer in our time…” Well, that’s not what I said.

I believe we can make exponential progress. I firmly believe we can do in the next five years what would ordinarily take ten. And think of what that will mean, of how many people you know who are saying, you docs are saying, “Doc, I just want to make it one more month to see my daughter get married.”
“Doc, doc if I can just make it another four months, I’ll be able to pay off the house and my wife will be okay when I go.”
“Doc, all I want to do is see my daughter graduate.”

These are real, real, real life situations: time matters. Days matter. Minutes matter. You all know that. We know the problem. Right now, there are 14 million new cases a year in the world, 8.2 million cancer related deaths worldwide per year.

The projections are, by 2025 if we stay on the exact course we’re on now, making the progress we’re making now, there will be 20 million new cases a year, and 11.4 million deaths from cancer alone.

Again, this is preaching to the choir, but unlike other diseases, you all know there are over 200 distinct types of cancer that we’ve identified, which makes cancer far more complicated disease, to treat and understand.

Cancer is taking loved ones from us and robbing us of decades of their lives. When I announced the decision to not run for president, by the way, I learned, if you want to become a really popular elected official, announce that you’re not running for president. It’s amazing what’s happened.

If I’d known this, I would’ve announced every year I wasn’t running.

But after Beau passed, Jill and I concluded we couldn’t. Anyway, I said in the announcement, because I was expected to make a formal announcement one way or another, I said that—it wasn’t written on the page, it was spontaneous—I said that my regret was that if I could do anything I would’ve wanted to be the president who ended cancer as we know it, because I think it’s possible.

My mom had the expression, “A little bit of knowledge is a dangerous thing.”

Any time your loved one, someone you care about, someone who’s part of your soul, part of who you are is in trouble, all of you do the same exact thing: you try to learn as much about the thing causing that person the trouble. You try to learn as much as you can.

I had some great tutors; great hospitals we were in: MD Anderson, Jefferson, Walter Reed—I mean I had great tutors.

That cancer moonshot grew out of a sentiment that I acquired, that we’re on the cusp of an awful lot of change.

Shortly after, at the State of the Union, the president didn’t even tell me, but he announced at the State of the Union that Biden’s doing a moonshot. When I first heard it, I thought he wanted me to get in a capsule and head to the moon, but he’s one of my best friends.

He asked me to lead this sector. But he didn’t just ask me to lead it, he gave me authority, like he did in the Recovery Act, authority over all the cabinet positions, as if he were doing it, to engage the entire federal government, every cabinet agency that has any impact possible impact on the fight against cancer, from outfits like the NIH which you immediately associate with to Department of Energy.

I’ve traveled the country and the world, touching many of the major nerve centers in the fight against cancer to get the ideas of the experts. Is it possible, can we double the rate at which we make progress?

By the way, regardless of where I am, I do an awful lot of foreign policy. I’m referred to as a foreign policy expert. You know that old joke: an expert is someone from out of town with a briefcase.

I did not bring my briefcase. I know a hell of a lot more about foreign policy than I do or did, particularly at the beginning about the fight against cancer.

I was recently in the Middle East, talking about ISIS, and, in the Gulf, with one of the leaders, and I thought we were going to have this long discussion.

I brought my entire foreign policy team, my national security advisors; he had his whole team sitting on this beautiful dock outside at one of these
palaces. And he starts off and says, “Can you talk about cancer?”

When I was in Jordan, when I was in Israel, Japan, South Korea, working on [memoranda of understanding] at each one of those countries, they all said that they want to be part of this effort.

I’ve been stunned, stunned, stunned at the response to the president’s announcement. Just evidence, nothing about me or the president. It’s about the intensity with which people feel about this subject, and the overwhelming desire to have some concrete hope of distant changes.

Whenever I go, when I talk about what’s possible with fighting cancer, there’s a consensus that we’ve reached an inflection point.

Let me explain what I mean by that:

Five, six years ago, oncologists weren’t routinely working with immunologists, virologists, chemical engineers, biological engineers—but now, they are.

Secondly, there is a recognition that by aggregating and sharing data of millions of patients, including genomics, family history, lifestyle, treatment outcomes. We have the potential to find new patterns and causes and successfully treat cancer in ways we never did before. We can now do a thousand billion calculations per second.

It changes the world, potentially. [Through] aggregating data we can learn. Now we have the capability to do with advanced technology and super computers. Supercomputing allows us to analyze enormous amounts of data to find answers we couldn’t do five years ago. It would take scores and scores and scores of experts years to pour over them and find similar patterns.

And there’s new hope, new treatments like immunotherapy training the immune system to attack cancer cells more accurate radiation therapies that target cancer cells but do less damage to the healthy cells.

Transforming many of the types of cancer into chronic and manageable diseases, when ten years ago they were literally a death sentence. But in my view, to seize the moment, to seize this inflection point, we have to improve how we work together and get this all within our reach.

One of the biggest problems we have in my view to solve is treatments need to be affordable.

We need a strong continuum for generating, using knowledge to fight cancer and we have to change the entire path in my view of how knowledge goes to small labs to pharmaceutical companies to production facilities.

And the cost of lifesaving drugs is astronomical. We have to come up with a better way. What is the possible justification when a drug a lifesaving drug is brought to market at the time it’s brought to market it costs $26,000 a year, and 15 years later it costs $120,000? Tell me, tell me—tell me, what is the justification for that?

I’m sure you can identify a lot of other examples, and I know there are hundreds of millions of millions of dollars in sunken costs that come up with nothing.

They have to be accounted for, but I want to raise some questions here and I want to get some answers. When I began the moonshot effort, I was committed to bringing together all of the human financial and knowledge resources we have to break down silos to seize the moment and to double our rate of progress, but I’m also committed to doing everything in my power to change the culture that too often stifles that progress.

Quite frankly, we have to change the culture a little bit. There was a report in Stat News that although NIH funding for cancer trials requires the funding. When you get the funding, NIH requires the results of that data being reported instantly. Yet, a number of institutions that receive the most funding from NIH don’t report back to NIH in a timely fashion—sometimes a year or more.

NIH scientists themselves, 75 percent of the time were late or don’t report their results.

That’s the study. It may be wrong. And I hope the experts here will tell me that’s incorrect, but under the law it says you must report. If you don’t report, the law says you shouldn’t get any funding.

Doc, I’m going to find out if that’s true, and if that’s true I’m going to cut funding. That’s a promise. That’s a promise, because all that does is slow progress.

To change the culture, the moonshot effort has got to take part in a few missions. We have to reclaim the incentive for research within the research system, promote breakthroughs and faster progress in preventing and treating cancer.

We have to change the culture of research that turns scientists into grant writers, discouraging risk-taking. We have to change your academic and publication system, to reward teamwork and results for patients, not just raw numbers of publications and awards that are granted.

And by the way, I said this to 6,000 researchers, hosted by an organization in one of the other cities. Notice the heads of the organization were a little bit
dismayed when two thirds of the audience stood up and clapped. Not a joke: we need to be sure that research studies are available as soon as they are published so the field can move forward.

We have to generate, and share, and integrate data with the ultimate goal of enhancing patient care.

We have to create better systems to share data and to empower patients to share and use their data in a way they want to.

In other sectors like physics and aerospace, scientists share complex information seamlessly and ubiquitously all the time, but somehow, I guess because of hundreds of years of tradition, not in medicine.

Maybe there’s an explanation; I haven’t heard it yet.

We have to bring new prevention strategies and diagnostics and therapeutics to patient communities around the world.

The first place I’m going after this summit is to Cleveland, to highlight a tobacco cessation and cancer screening program, and a collaboration between George Washington University and Case Comprehensive Cancer Center at Case Western Reserve University.

Both Washington and Cleveland have higher-than-national-average smoking rates—lung cancer rates are higher, especially in areas where few people have access to cancer screening.

This problem, which you’ll hear more about this morning, uses social media and digital monitoring technologies to help people adapt to healthier lifestyles.

You all know the numbers better than I do. Prevention can save a whole hell of a lot more lives than anything else we can do. Other screening programs are becoming available that detect cancer early so that it can be treated with a better chance of success.

These new approaches include non-invasive and mobile imaging techniques, new genetic markers that allow us to identify those at risk of developing cancers long before they develop.

I’ve been to most every major cancer institution in the country. Some of the work you’re doing is absolutely mind blowing. Liquid biopsies are getting a whole lot of attention, and may provide an even better way to screen for cancer very early in the process with a simple blood test.

We can reach more people by taking screening into their communities, just like we did I might add with breast cancer and HIV. We have mobile vans rolling in all of those communities. We have mobile vans rolling in every one of your cities.

As these techniques become more and more available and more precise, there’s a lot we can do.

Finally, we have to accelerate getting treatments to patients by identifying any unnecessary regulatory barriers that exist on the federal level that stand in the way of improving research or care.

For example, patients should be able to seamlessly find a clinical trial that might suit a specific condition. Doctors should have an easy way of guiding their patients through the process.

But as you know, less than 4 percent of cancer patients are enrolled in trials that might be key to discovering the next lifesaving treatment.

I’ve been to Washington State, I’ve been to Nevada, I’ve been to California, I’ve been in Florida, I’ve been to 11 of the most highly-funded and most reputable cancer research centers in the world. And they talk about how can they will they be able to get this lifesaving capacity out to rural communities, Indian reservations.

The one thing about you docs is, you became docs for a reason, you’re devoted, you care, you care a heck of a lot.

It surprised me and pleased me to see how intensely the medical community was talking about the need to get services to at-risk communities that weren’t available right now.

Online clinical trial database has proven to be far too complicated for most patients and most local oncologists to be able to navigate. So under the moonshot we’re creating a new trials.cancer.gov to help people learn about and get access to cancer trials.

It will also be, I hope, a significant benefit to the pharmaceutical companies who are conducting trials and many times have trouble finding enough people to be in the trials.

As advanced as we are, the idea that we can’t come up with an app that is accurately able to be used and has all this data on it is surprising to me. When we put in the Recovery Act, the president asked me to manage almost a trillion dollars: $840 billion. We spent 18 months, and, by the way, from every outside study, with less than 0.2 percent in outside waste or fraud.

And in that, we thought we were going to change the way we governed, and we decided that electronic recordkeeping would help the medical community a great deal.

So we put $35 billion in. It all got spent.

Guess what? The five different systems can’t talk to one another, I mean think about it. Now we’re not computer scientists.

My son Beau, he was in a trial of one—anti-PD1
and a viral injected into his stage IV glioblastoma—requiring him, on a multiple times in a day, to do an MRI to see the progress.

At first, our docs were giddy at the progress being made. But he was up at Walter Reed, and the docs were down at MD Anderson, an incredible organization in my view.

But for the fact my son-in-law is a leading surgeon in the Philadelphia area, we had to gather up the information not recorded electronically, get on a plane, and fly it down.

Joe could you imagine your company functioning that way and being able to make it? It’s not anybody’s fault, but we’ve got to fix it. We’ve got to fix it.

We owe it future generations to seize this moment, to move with deliberate purpose and double our rate of progress and just deal with the things that if this were a high tech firm we were running, they’d say we’ve got to solve this problem. It’s within our wheelhouse to do these things.

What I’m talking about doesn’t even contemplate the enormous genius that is in this room.

One of the brightest men in all of medicine is sitting right there—the head of NIH. I mean it sincerely. The impediment isn’t the lack of the gray matter genius and ingenuity in terms of new drugs, new treatments, etc. It’s all this stuff that gets in the way.

The only thing I’m good at in government is getting things out of the way. I don’t want this to come across as somehow the federal government has the answer. We don’t have the answers. We’ve got to figure out how to get out of your way and you guys have to figure out how to get in each other’s way more.

Previous generations successfully faced similar problems in giving us longer lives to enjoy today, and millions of people feared that their children during the Polio epidemic of the 50s, but hope conquered fear sooner than anyone had ever imagined with technology and breakthroughs with the polio vaccine.

Look what you’ve all done in HIV/AIDS, and how you’ve aggregated the capability and the progress.

Cancer is not going to be conquered by any one thing, but I believe it’s a challenge with your brilliance we can win if you’re devoted to winning it in a timely fashion, meaning yesterday.

Today, we’re announcing a series of measures being implemented by private agencies, companies, universities, institutions, and foundations that address some of the problems and move us toward a goal of doubling that rate of progress.

The federal task force has gotten to work, and today is announcing a dozen new actions of policies including the Department of Energy and Veteran’s Affairs have now formed a collaboration to form the most powerful computational assets at the national labs to nearly half a million veterans records in one of the world’s largest research cohorts.

The Million Veterans Program, a cornerstone of the president’s precision medicine initiative.

The National Institute of Health is launching a new partnership bringing together twelve biopharmaceutical foundations and philanthropies to invest together to fund research to make all the resulting data available to everyone, ultimately bringing new therapies to patients in less time.

Earlier this month, I went to the University of Chicago for the launch of the National Cancer Institute Genomic Data Commons, a platform that includes genomic data, associated clinical trials that are shared openly and broadly to advance cancer research and improvement.

We’re announcing today that with commitment from Foundation Medicine, a total number of patients has gone from 32,000 patients have accumulated, doubled the 32,000 in just over a month.

The expectation and hope is that it’ll be exponential. Private, philanthropic, academic, patient advocacy communities have answered the call including the Breast Cancer Research Foundation, inspired by the moonshot I’m told, called for collaboration and commitment is doubling their annual research investment from $50 million to $100 million, aiming for an accumulative investment of $1 billion by 2021 to speed up connecting the dots, as they say.

Between molecular information we can amass and our understanding of cancer to accelerate turning new discoveries into effective treatments. OPeN, the Oncology Precision Network, a partnership between Intermountain Healthcare, Stanford Cancer Institute, Providence Health Services, Catholic Health Initiative, the Henry Ford Health System and Syapse.

This network is going to link cancer genomic data for 79 hospitals and 800 clinics across 11 states, data for more than 50,000 more cancer patients per year that can now be shared openly on a network.

A company called DocGraph will use Medicare claims data released because of the use of the administration’s open data effort to publish reports describing Medicare patients, how they move through the healthcare system, in years before and immediately after a cancer diagnosis.

The report will show how factors such as
geography, type of physicians, and providers they see, their treatment, their pathways, effect the patients experience and effect the outcomes.

Through a collaboration between Destination Brands International and Mt. Sinai Medical Center, the City of Miami Beach providing dozens of free sunscreen dispensers on their beaches, their parks, their public pools for residents, for millions of visitors every year. I might add parenthetically, there’s been no progress in sunscreen, in new sunscreen applications; I don’t know this for a fact, for almost two decades. That’s a long time.

In response to Cancer Moonshot, the focus on prevention Miami beach is going to continue this program at least until 2021. These are just some examples.

There are 30 other announcements we’re making today. In the early 1900s, a bone surgeon in New York named William Cooley following pioneers like Koch and Pasteur and von Behring developed a theory that most surgical infections, post-surgical infections, helped patients recover better from cancer by provoking the immune system response.

He began injecting patients with Streptococcus and dead bacteria, which became known as Cooley’s toxins.

When he did, the patients survived a little bit longer. Following pioneers like Cooley, scientists developed immunotherapies that have the chance of making some cancers a distant memory.

Imagine a day, perhaps when my grandchildren have children of their own, when the threat of cancer is a distant memory, when their children can be vaccinated for cancers as routinely as being vaccinated for measles and mumps. And other cancers can be treated and cured, made into chronic conditions.

Folks, I’ve spend the better part of the last year trying to learn as much as I possibly can to become as informed as I possibly can, and yet I’m not as informed as many of you in the audience.

I can tell you more about the SS-18 Soviet silo missile than I can about some cancers, but I’ve worked hard, I’ve gotten a lot of help. I think I’m in a position to say without being totally naïve that we’re on the cusp of breakthroughs that can get us there.

The goal of the moonshot is to propel us forward today. Supporters and skeptics alike ask us, “What’s the moonshot?”

Moonshot is all of you, people listening in these all around the country.

All of you jumping in and doing what you can to help prevent, change lifestyles, detect, treat cancer. It’s everyone who is spending nights and weekends in their labs looking for the next breakthrough, it’s the patients who are being treated for their cancers hoping they can return to their lives and their families.

It’s patients starting foundations and companies to develop cures for their children. It’s organizations like the NIH and the Department of Energy, and as small as Alex’s Lemonade Stand trying to understand cancer and help patients defeat it.

The Moonshot is carrying the hopes and dreams of millions of people who want us to succeed, make a difference in their lives and their families. Not someday, but now.

The work we’re doing and the work we’re doing together I think we’ve fulfilled many of those hopes. Cancer touches everyone in some way. We all have reasons for being here. Survivors, patients, families, friends, physicians, researchers.

Almost every one of us in here has lost someone relatively close to us.

We’re all here because we can do something about it. And that’s what Jill and I had decided to do when our so Beau passed.

Part of the moonshot is my view from my perspective internally of Beau, and the life he lived of courage, and never giving up hope. This isn’t about him, this isn’t about a single person, it’s about us not giving up hope and having the urgency of now.

I won’t mention the particular agency, but we’ve had, one of the agencies in the federal government said they’re going to get a new director, and said “We’ll have it by the end of 2016.”

I called the head of that department in and said, “[End of] 2016? It is now June. If you can’t get that director in the next four months, tell me, we’ll go find someone else who can find them.”

It’s bizarre.

Some of your actions are like that: we can do it later.

Because these are breakthroughs that are just beyond our grasp. We need each and every one of you, I challenge all of you, to think anew about the scourge of cancer.

Go beyond your comfort zone. Set and achieve goals that are going to change the way we do this. Think about it tomorrow.

Look, I’ll conclude by saying that I know I’m maybe I’m sometimes accused, with total justification, of being too passionate about the things I care a lot about.
In Brief
Haakon Ragde Named ASTRO 2016 Honorary Member

HAAKON RAGDE was named the 2016 Honorary Member of the American Society for Radiation Oncology, the highest honor ASTRO bestows on members in disciplines other than radiation oncology, radiobiology or radiation physics.

Ragde will be inducted during an awards ceremony at ASTRO’s 58th Annual Meeting, Sept. 25-28 in Boston. Ragde is the 33rd physician to be chosen for the honor.

“Dr. Ragde is a luminary in the field of medicine,” said ASTRO Chair Bruce Minsky. “His work has become the standard of care in a number of areas. As a board certified urologist, he has an impressive array of achievements, including introducing seed implantation for prostate cancer into the U.S., introducing transrectal ultrasonography and introducing the transrectal ultrasound-guided prostate biopsy method now used. He also took part in bone marrow transplant research that earned researcher E. Donnall Thomas, MD, the Nobel Peace Prize for Physiology or Medicine in 1990. ASTRO thanks Dr. Ragde for his outstanding accomplishments.”

He accepted a staff position in 1965 in general surgery and urology at the University of Washington. There, Ragde and a colleague performed the first successful kidney transplants in the state of Washington. However, following these procedures, he was unable to raise money for continuing research. So when Thomas, the hematology professor who would ultimately win the Nobel Prize, approached Ragde with an offer to join Thomas’ bone marrow transplantation research team, Ragde agreed.

The team—Thomas, Ragde and two internists, Ranier Storb and Robert Epstein—studied how bone marrow transplantation might cure leukemia and other cancers of the blood by replacing the diseased marrow with healthy marrow. Ragde said the Nobel Peace Prize for the research did not surprise him. Not only did the five years of work change his life, but he also became good friends with Thomas.

According to Ragde, his greatest career accomplishment was template-directed brachytherapy for prostate cancer. He opened a private practice in urology in Seattle following his work with Thomas and became an expert in transrectal ultrasonography of the prostate. Ragde was trained in the technique by physicians at the University of Copenhagen,
Copenhagen, Denmark and Kyoto University, Kyoto, Japan. His mentor in Denmark called him to Copenhagen to see the accurate placement of ultrasound-directed radioactive seeds into a cancerous prostate. Ragde then took the technique back to his practice in Seattle.

Ragde established the Pacific Northwest Cancer Foundation (which created Northwest Biotherapeutics Inc.) and the Haakon Ragde Foundation for Advanced Cancer Studies. He retired from active practice in 2003 and now researches immunotherapy. He is conducting a study on immunotherapy on advanced prostate cancer patients at the University of Bergen in Norway.

**STEVEN PAUL** was elected chairman of the Foundation for the National Institutes of Health.

Paul succeeds Charles Sanders, who has served as chairman since 1997 and will remain a member of the board. In addition, **Thomas Insel** and **Paul Stoffels** were elected as new board members.

Paul is president and CEO at Voyager Therapeutics, Inc., as well as a venture partner at Third Rock Ventures. Prior to Voyager, Paul was founding director of the Helen and Robert Appel Alzheimer’s Disease Research Institute, the Burton P. and Judith B. Resnick Distinguished Professor in Neurodegenerative Diseases and a DeWitt Senior Scholar and professor of neuroscience, psychiatry and pharmacology at Weill Cornell Medical College. Paul also spent 17 years at Eli Lilly and Company, where he was president of the Lilly Research Laboratories. Prior to Eli Lilly, Paul served as scientific director of the National Institute of Mental Health.

Insel is the director of clinical neuroscience at Verily, an Alphabet company, formerly known as Google Life Sciences. Insel served as director of the National Institute of Mental Health from 2002 to 2015, overseeing advances in mental health, neuroscience, diagnostics and therapeutics.

Prior to his appointment at the NIMH, Insel was a professor in the Department of Psychiatry and director of the Center for Behavioral Neuroscience at Emory University School of Medicine. He also served as director of the Center for Autism Research and is a member of the scientific advisory board at the Autism Science Foundation.

Stoffels is chief scientific officer at Johnson & Johnson’s Global Public Health unit.

**STEPHEN BURLEY** was named as co-program leader of the Cancer Pharmacology Research Program at Rutgers Cancer Institute of New Jersey.

Burley will work with co-program leader X.F. Steven Zheng, a university professor at Rutgers Robert Wood Johnson Medical School, in determining the mode of action and mechanism of resistance to anti-cancer agents and developing novel concepts and strategies for cancer treatment.

Burley has been a full research member of Rutgers Cancer Institute since 2013. He is the director of the Center for Integrative Proteomics Research, founding director of the Institute for Quantitative Biomedicine, and a distinguished professor of chemistry and chemical biology in the School of Arts and Sciences at Rutgers University. He also serves as director of the Research Collaboratory Structural Bioinformatics Protein Data Bank.

**FIRAS ELADOUMIKDACHI** was named program director for the Rutgers Cancer Institute of New Jersey at Hamilton. He will be responsible for clinical leadership of the oncology service line at RWJ Hamilton including medical, surgical and radiation oncology.

Eladoumikdachi is an assistant professor of surgery at Rutgers Robert Wood Johnson Medical School. He has been with RWJ Hamilton and the Stacy Goldstein Breast Cancer Center at Rutgers Cancer Institute in New Brunswick for the past year. Prior to that, Eladoumikdachi served as the director of the breast program at Genesis Health Care System in Ohio and vice chair of Ohio Integrated Care Providers.

**JOEL KATZ** was honored by City of Hope with the Spirit of Life Award.

Katz, an entertainment attorney, is chair of the Global Entertainment and Media Practice of Greenberg Traurig, and was recognized for his work in the entertainment industry. Katz will be presented with the award at a gala in Los Angeles Nov. 10.

“City of Hope is proud to honor Joel this year in recognition of his support of our mission,” said Robert Stone, president and CEO of City of Hope. “We deeply appreciate Joel’s unwavering commitment to our Spirit of Life campaign which propels our innovative research and treatments that outsmart deadly diseases—one patient at a time.”
THE AMERICAN CANCER SOCIETY plans to double its annual funding for research by 2021. The society made the announcement in conjunction with Vice President Biden’s National Cancer Moonshot Summit at Howard University in Washington, D.C.

ACS plans to increase its annual research investment to approximately $240 million by 2021. The organization currently spends about $100 million per year in new grants to academic research institutions and another $15 to $20 million annually in research by ACS investigators in cancer epidemiology, surveillance and health services, behavioral research, and economics and health policy.

ACS has invested $4.5 billion in research since 1946. According to the society, 47 of its funded researchers have won Nobel Prizes for their work.

RESEARCH!AMERICA launched its Campaign for Cures 2016 election blog and an online interactive map featuring hundreds of quotes on medical progress from candidates across the political spectrum running for national office.

Managed by former USA Today senior editor and health reporter Janice Lloyd, the blog features election news, survey data, commentary and analysis of presidential and congressional races in key states on topics relevant to medical progress.

Campaign for Cures partners include Pfizer, the Society for Neuroscience, Alzheimer’s Association, PhRMA, American Heart Association, American Cancer Society Cancer Action Network, University of Maryland School of Medicine, The University of Chicago Pritzker School of Medicine, American Public Health Association, American Association for Cancer Research, Cold Spring Harbor Laboratory, EveryLife Foundation for Rare Diseases, The American College of Neuropsychopharmacology, Penn Medicine, The Whitehead Institute and The American Association of Colleges of Pharmacy.

MOUNT SINAI HEALTH SYSTEM and Valley Health System plan to form a partnership that will enable Valley to access Mount Sinai’s roster of clinical trials, as well as develop new programs and services.

In December 2015, Valley and Mount Sinai announced plans to collaborate on clinical programs, research and educational offerings. Mount Sinai and Valley plan to work together at Valley’s Blumenthal Cancer Center in Paramus and the main campus in Ridgewood by establishing a linked clinical information system.

According to Robert Korst, medical director of Valley’s Blumenthal Cancer Center, among the first Mount Sinai clinical trials that Valley patients will have access to include new treatments and treatment protocols for cutaneous malignancies, including melanoma and other skin cancers; genitourinary malignancies, including prostate and kidney cancers; and hematologic cancers and serious blood disorders, including leukemia, lymphoma, multiple myeloma and myelodysplastic syndromes. Some treatment protocols will include bone marrow transplantation and immunotherapeutic vaccines.

IBM Research will undertake research with Melanoma Institute Australia to help further advance the identification of melanoma using cognitive technology.

This research builds on IBM’s existing research agreement with MoleMap, which uses advanced visual analytics to analyze more than 40,000 data sets including images and text. IBM Research plans to analyze dermatological images of skin lesions to help identify specific clinical patterns in the early stages of melanoma. The Australian research team aims to help reduce unnecessary biopsies and help clinicians more accurately understand skin cancer, which could help to improve patient care.

THE WISTAR INSTITUTE has entered into an agreement with the Gene Editing Institute at Christiana Care’s Helen F. Graham Cancer Center & Research Institute, expanding their previous partnership established in 2011.

The Gene Editing Institute will be integrated into Wistar’s Molecular Screening Facility. The Gene Editing Institute will retain its management structure and will remain located at the Graham Cancer Center on the Christiana Hospital Campus in Newark, Del. The Molecular Screening Facility will remain housed at Wistar in Philadelphia. According to the two organizations, they have already begun scientific collaborations involving research on melanoma and lung cancer. The previous partnership was the first inter-institutional affiliation between an NCI-designated basic research institution and a community cancer center.
Drugs and Targets

FDA Approves Epclusa For Adults with Chronic Hepatitis C

FDA approved Epclusa to treat adult patients with chronic hepatitis C virus both with and without cirrhosis. For patients with moderate to severe cirrhosis, Epclusa is approved for use in combination with the drug ribavirin.

Epclusa is a fixed-dose combination tablet containing sofosbuvir, a drug approved in 2013, and velpatasvir, a new drug, and is the first to treat all six major forms of HCV.

The safety and efficacy of Epclusa for 12 weeks was evaluated in three phase III clinical trials of 1,558 subjects without cirrhosis or with compensated cirrhosis. Results demonstrated that 95-99 percent of patients who received Epclusa had no virus detected in the blood 12 weeks after finishing treatment, suggesting the patients’ infections had been cured. The safety and efficacy of Epclusa was also evaluated in a clinical trial of 267 subjects with moderate to severe cirrhosis, of whom 87 subjects received Epclusa in combination with ribavirin for 12 weeks, and 94 percent of these patients had no virus detected in the blood 12 weeks after finishing treatment.

Epclusa carries a warning for patients and health care providers that serious slowing of the heart rate (symptomatic bradycardia) and cases requiring pacemaker intervention have been reported when amiodarone is used with sofosbuvir in combination with another HCV direct-acting antiviral. Co-administration of amiodarone with Epclusa is not recommended. Epclusa also carries a warning not to use with certain drugs that may reduce the amount of Epclusa in the blood which could lead to reduced efficacy of Epclusa.

Epclusa was reviewed under the FDA’s priority review program, which provides for an expedited review of drugs that treat serious conditions and, if approved, would provide significant improvement in safety or effectiveness.

FDA granted a fourth Breakthrough Therapy Designation to Imbruvica (ibrutinib) as a potential treatment of chronic graft-versus-host-disease after failure of one or more lines of systemic therapy. The agency also granted the therapy Orphan Drug Designation for the condition.

The request was based on preliminary clinical data from a phase I/II study evaluating the safety and efficacy of Imbruvica for the treatment of patients with steroid-dependent or refractory cGVHD. Overall, Imbruvica has shown compelling preclinical data, a novel mechanism of action and promising early clinical efficacy data supporting an improvement in cGVHD based on the NIH consensus cGVHD Activity Assessment. Preliminary results from this trial were previously presented at the 42nd Annual Meeting of the European Society for Blood and Marrow Transplantation in April and the 51st American Society of Clinical Oncology annual meeting in May 2015. Imbruvica is sponsored by AbbVie.

FDA granted Fast Track Designation to ets-family inhibitor TK216 in Ewing sarcoma patients that have relapsed or are refractory to standard of care therapy.

Oncternal Therapeutics Inc., the drug’s sponsor, is in the process of initiating a first-in-human phase I trial in relapsed or refractory Ewing sarcoma.

TK216 is a first-in-class small molecule that inhibits the biological activity of ets-family transcription factor oncoproteins in a variety of tumor types, stopping cancer cell growth and tumor formation, according to the company. In Ewing sarcoma, it is designed to target a single and well-characterized genetic mutation that causes the disease.

Hetero launched biosimilar bevacizumab in India for the treatment of metastatic colorectal cancer under the brand name Cizumab.

The product has been approved by the drug controller general of India and has been recommended as a first-line treatment for mCRC. The product will be made available to patients in a single dose vial with two strengths, 100 mg and 400 mg. It will be marketed and distributed by Hetero Healthcare Ltd.

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Novartis entered into a collaboration and license agreement with Xencor Inc. to develop and commercialize novel therapeutics, including XmAb 14045 for acute myeloid leukemia, and XmAb 13676 for B-cell malignancies. Both are expected to begin development this year.

Under the terms of the agreement, the parties will collaborate and share development costs for the worldwide development of XmAb14045 and XmAb13676, with Xencor maintaining U.S. commercialization rights and Novartis having commercialization rights in the rest of the world. Novartis will receive worldwide rights to Xencor’s bispecific technology to develop and commercialize four additional targets selected by Novartis, one of which Xencor may elect to co-detail in the U.S. The bispecific collaboration will include molecular engineering by Xencor. Additionally, Novartis will receive a worldwide non-exclusive license to use Xencor’s XmAb Fc technologies in up to ten molecules. Xencor will receive a $150 million upfront payment and is eligible to receive clinical, regulatory and sales milestone payments for successful programs.

OmniSeq, a subsidiary of Roswell Park Cancer Institute, received New York State Clinical Laboratory Evaluation Program approval for its OmniSeq Comprehensive panel, a 144 gene, pan-cancer, next-generation sequencing tumor profiling diagnostic panel to guide oncology treatment decision-making.

“OmniSeq is proud to receive New York State CLEP approval for OmniSeq Comprehensive. CLEP is the highest standard of Clinical Laboratory Improvement Amendments laboratory validation,” said Carl Morrison, president and chief scientific officer of OmniSeq and executive director of the Roswell Park Center for Personalized Medicine.