*Linda Payne was diagnosed with myelodysplastic syndrome (MDS)*

# Value and Innovation

## 2018 REPORT

**This report is intended for U.S. government officials, other healthcare policy makers and healthcare policy opinion leaders**

Celgene

# Message from the Chairman and CEO

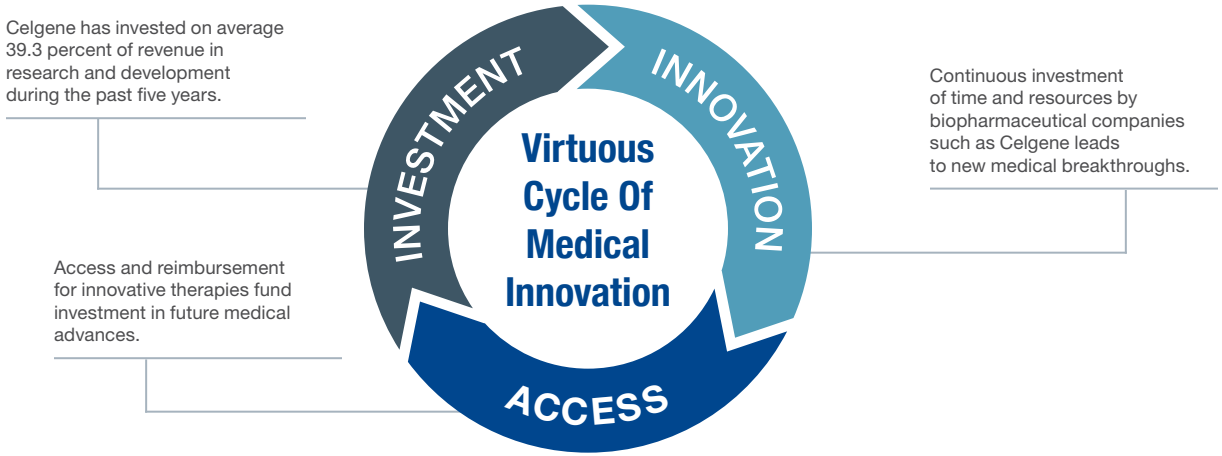
# To Our Stakeholders

A few decades ago, drug discovery was, for the most part, a matter of trial and error. The world's most successful pharmaceutical companies would often collect dirt from far-flung locales and screen that soil or sand for medically active components. Biology was often a secondary concern. It was the speed of trial and error that was important.

Today, drug discovery is more targeted and intentional, building on a wealth of data that has grown exponentially since the early days of trial and error. Our knowledge of cell biology and genomics is now sufficiently advanced that it is possible to create medicines based on our individual immune cells or genetic profile. These advances promise patient-tailored medicines, such as the new CAR T therapies that "train" the patient's own immune system to fight cancer, that have the potential to transform how cancer is treated.

**THE VIRTUOUS CYCLE OF INNOVATION[1]**

ACCESS AND REIMBURSEMENT FOR INNOVATION TODAY MAKE POSSIBLE THE INVESTMENT IN RESEARCH AND DEVELOPMENT THAT LEADS TO FUTURE MEDICAL ADVANCES.




This kind of innovation, however, requires investment to be sustained. Both the basic science and the delivery of treatments require investment to foster the next generation of therapies. The challenge is ensuring access to and reimbursement for those new medicines, thereby enabling innovators to reinvest in research and development. This is the virtuous cycle of innovation.

If the costs of a new intervention far exceed the benefits, or if patients cannot get access, we've failed – as a system – to provide value. Conversely, when we see benefits that far outstrip costs, we can be confident that we are moving the health system in a direction to higher value, with better health and lower costs.

Understanding that balance has never been more critical. The United States spends $3.3 trillion on healthcare every year, or 18 percent of the nation's GDP.[2] That's about equal to the entire GDP of Germany.[3] Among the primary drivers of this spending are hospital care (32%); physician and clinical services (20%); retail prescription drugs (10%); and other health, residential, and personal care services (5%).[4] We have a responsibility to make sure that those dollars are spent wisely and to define what we – as a company and as a part of the healthcare system – believe is a good investment in the health of the nation.

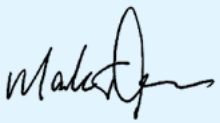
This report is an effort to help meet that responsibility. In it, we have defined our role as "value drivers" by outlining the different ways that Celgene contributes value: to patients, to the health system, to the economy and society, and to future innovation.

Though spending on biopharmaceutical products remains a relatively small piece of the overall healthcare environment, the biopharmaceutical sector has had an outsized impact

on outcomes, and we are proud of our role in a therapeutic revolution that has cut the cancer death rate by 25 percent since 1991.[6] While overall spending on biopharmaceutical products has indeed increased over the years, it has contributed to significant improvements in health outcomes. In fact, one study found that over 70% of recent life expectancy growth is due to the increased use of medicines.[7]

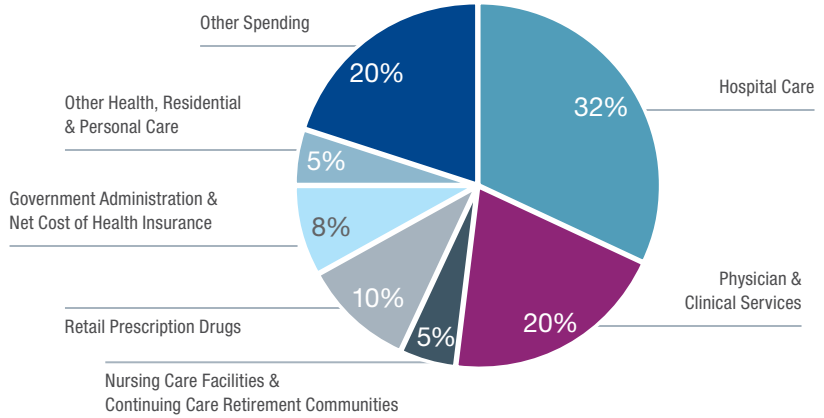
Even with the increasing innovation coming from the biopharmaceutical sector, there are signs that drug spending is stabilizing. In 2017, per-person spending on prescription drugs rose just 1.5% across plans covering employees and their families, less than half of the increase reported in 2016 and the lowest increase in 24 years of tracking drug-trend data.[8] Another study found that after accounting for rebates and discounts, net spending growth on prescription drugs in the U.S. slowed to 0.6% in 2017.[10]

But we cannot simply proclaim successes, declare that we have provided value, and avoid further discussion. Instead, we must start with a clear definition of our goals and a fair-minded examination of our impact at every level of the healthcare system. To do this, Celgene believes there should be holistic transparency throughout the system to track and assess how our healthcare resources are being allocated. This report, and past efforts such as the development of Celgene's Pricing Principles, are evidence of our commitment to transparency. We believe that, by providing this level of transparency, we will be able to evaluate our performance as "value drivers" and continually refine our role in the virtuous cycle of innovation.

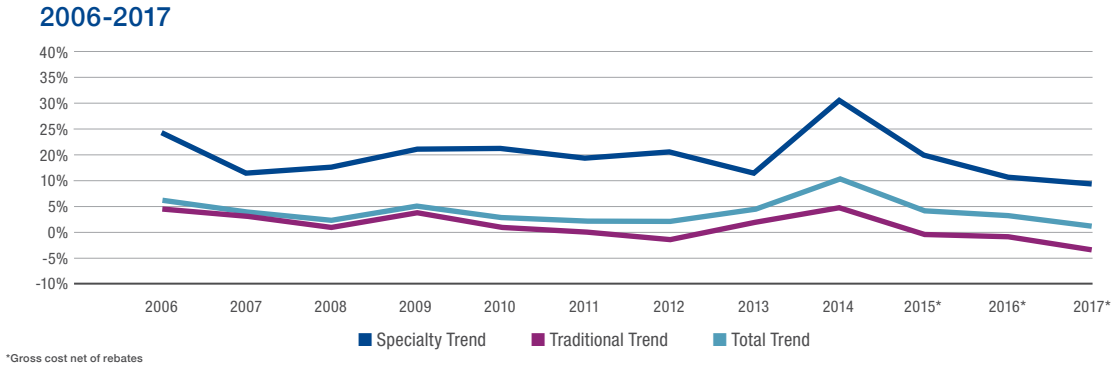


**Mark J. Alles**
Chairman and Chief Executive Officer

## BREAKDOWN OF 2016 U.S. HEALTHCARE SPENDING[5]

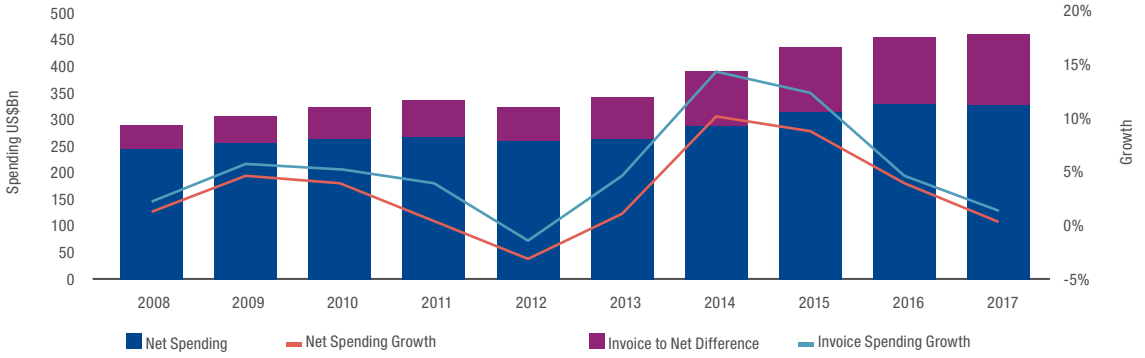



## CHANGE IN PRESCRIPTION DRUG SPENDING ACROSS COMMERCIAL PLANS[9]




*Gross cost net of rebates

## TOTAL SPENDING ON MEDICINES AND GROWTH IN THE U.S.[11]



# About This Report

# About This Report

Celgene's Value and Innovation Report is the first-ever examination of the different ways in which Celgene's pursuit of innovation creates value for patients, the health system, the economy and society, and future innovation. This report has been developed to contribute to the U.S. healthcare policy discussion. Therefore, it is intended for U.S. government officials, other healthcare policy makers and healthcare policy opinion leaders. Celgene will issue this report on an annual basis to track its progress using the value framework laid out below.

The Value and Innovation Report can be accessed online at: http://www.celgene.com/responsibility/business-with-integrity/

Other information about Celgene's perspective on the value of medical innovation can be accessed online at: http://www.celgene.com/value-of-medical-innovation/

Celgene's annual reports and other financial information are available at: http://ir.celgene.com/annuals-proxies.cfm

More information on Celgene's commitment to being a responsible corporate citizen can be found at: http://www.celgene.com/responsibility/

This report is intended for U.S. government officials, other healthcare policy makers and healthcare policy opinion leaders.


# Celgene Product Information

This report includes information related to the following Celgene therapies.

Revlimid® (lenalidomide) capsules

**For prescribing information for REVLIMID®, including Boxed WARNINGS, please visit:**
http://media.celgene.com/content/uploads/revlimid-pi.pdf

REVLIMID® is a registered trademark of Celgene Corporation.

Otezla® (apremilast) 30mg tablets

**For prescribing information for OTEZLA®, please visit:**
http://media.celgene.com/content/uploads/otezla-pi.pdf

OTEZLA® is a registered trademark of Celgene Corporation.

Pomalyst® (pomalidomide) capsules

**For prescribing information for POMALYST®, including Boxed WARNINGS, please visit:**
http://media.celgene.com/content/uploads/pomalyst-pi.pdf

POMALYST® is a registered trademark of Celgene Corporation.

IDHIFA® (enasidenib) tablets

**For prescribing information for IDHIFA®, including Boxed WARNING, please visit:**
http://media.celgene.com/content/uploads/idhifa-pi.pdf

IDHIFA® is a registered trademark of Celgene Corporation.

# Celgene's Approach to Value

# Celgene's Approach to Value

The idea of value in healthcare has moved in two different directions over the years. On the one hand, the concept has become more powerful as consensus has emerged that the healthcare system should be oriented around a measure of value, rather than the current volume-based approach. At the same time, how value is defined has become more nebulous, as different groups have emphasized different elements.

A recent study by the University of Utah describes this disconnect. Value to patients is largely a matter of affordable out-of-pocket costs, whereas physicians generally define value using statements that suggest that quality is the most important component.[12] Those who conducted the study suggest a definition that combines those two standards, with the addition of patient experience as the third relevant variable.

That does not mean that the word value lacks worth, only that all stakeholders, including Celgene, have a responsibility to be clear when we talk about value.

There is broad agreement that value is about optimizing healthcare outcomes while still controlling costs. To this end, we are seeing a gradual shift from a fee-for-service environment to a system that more directly ties spending on healthcare services to the outcomes they produce. Similarly, we are witnessing the development of value frameworks from various organizations such as the Institute for Clinical Economic Review, National Comprehensive Cancer Network, American Society of Clinical Oncology, American College of Cardiology and Memorial Sloan Kettering Cancer Center that seek to determine the cost effectiveness of different therapies and treatments.

While Celgene does not always agree with the methodology used by some of these value frameworks, we are very much in support of any transparent approach that is grounded in data but also takes into account other, sometimes harder-to-quantify, considerations that are important to healthcare stakeholders such as patient preferences and benefits to caregivers. We believe that value is constantly evolving and multidimensional. Any assessment that takes a narrow view of value is at risk of underestimating the benefits of a medicine to society and missing important societal cost offsets.

**DEFINING VALUE[13]**

TOP STATEMENTS
### PATIENTS VALUE MOST

My out-of-pocket cost is affordable **45%**

I'm able to schedule a timely appointment **39%**

I'm confident in the provider's expertise **38%**

The office is conveniently located **36%**

The provider knows and cares about me **36%**

TOP STATEMENTS
### PHYSICIANS VALUE MOST

I know and care about the patient **55%**

I order the appropriate exams, labs and imaging **55%**

The patient's health improves or stabilizes **50%**

I spend sufficient time with the patient **50%**

I include the patient in choosing treatment options **49%**

## Celgene's Principles for the Pricing of Innovative Medicines

At Celgene, we've taken a holistic and long-term approach to assessing the value of our innovative medicines and ensuring that this value is also reflected in the company's Pricing Principles.

**CELGENE'S PRINCIPLES FOR THE PRICING OF INNOVATIVE MEDICINES[14]**

### VALUE

The price of medicines should be based upon the benefits they deliver to patients, healthcare systems and society.

### INNOVATION

Pricing should provide incentives for continued investment in discovery and development of innovative medicines.

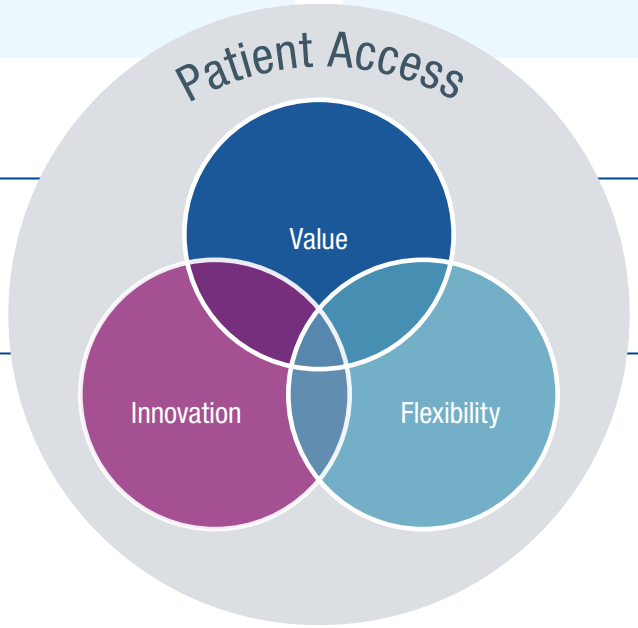
### FLEXIBILITY

Pricing flexibility among countries according to their financial circumstances permits broad global access.

### ACCESS

Patients who can benefit from Celgene products should have access to them.

Holistic approach …




… to value and pricing

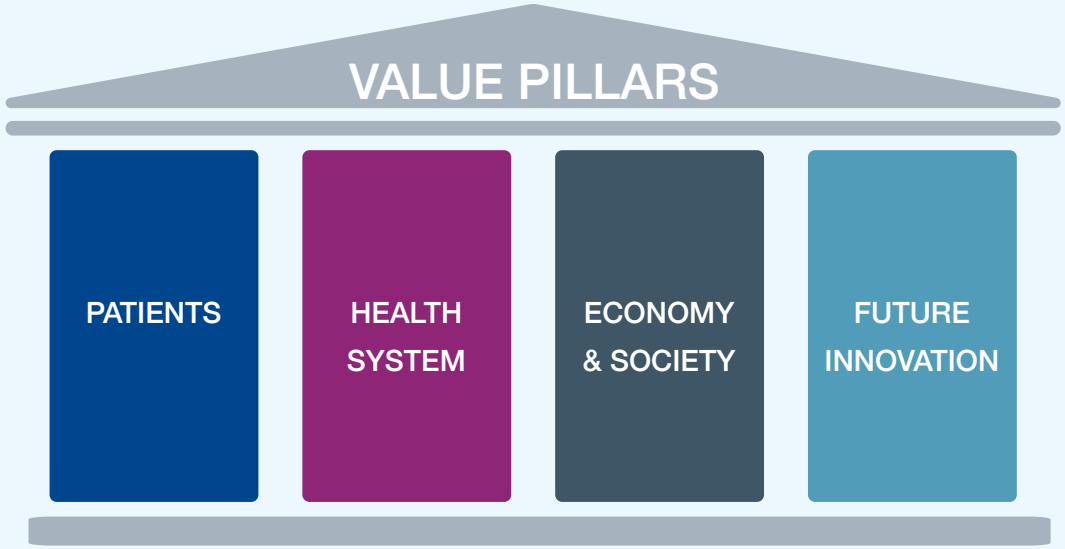
## Celgene's Value Pillars

It is our goal to both define clearly how Celgene measures value and to provide concrete examples of the value of our innovations. We believe that our therapies are capable of improving patient outcomes and quality of life, with benefits that can extend to the surrounding health system, the economy and even the perpetuation of innovation within our society. As such, we focus on the following four pillars of value in innovation:

1. Value to patients;
2. Value to the health system;
3. Value to the economy and society; and
4. Value to future innovation.

In order to enforce Celgene's commitment to provide insights about our progress and ongoing contributions to the healthcare system and society, we have developed four value pillars. In this first report, we will share some of the ways Celgene measures the value created by its innovations through the lens of these four value pillars.

**CELGENE'S VALUE PILLARS[15]**




***Lois Minta was diagnosed with psoriatic arthritis***

# Value to Patients

*Cindy Custodio was diagnosed with psoriasis and psoriatic arthritis*

# Value to Patients

## First and foremost, Celgene defines value through improved health outcomes and quality of life that its innovations offer patients.

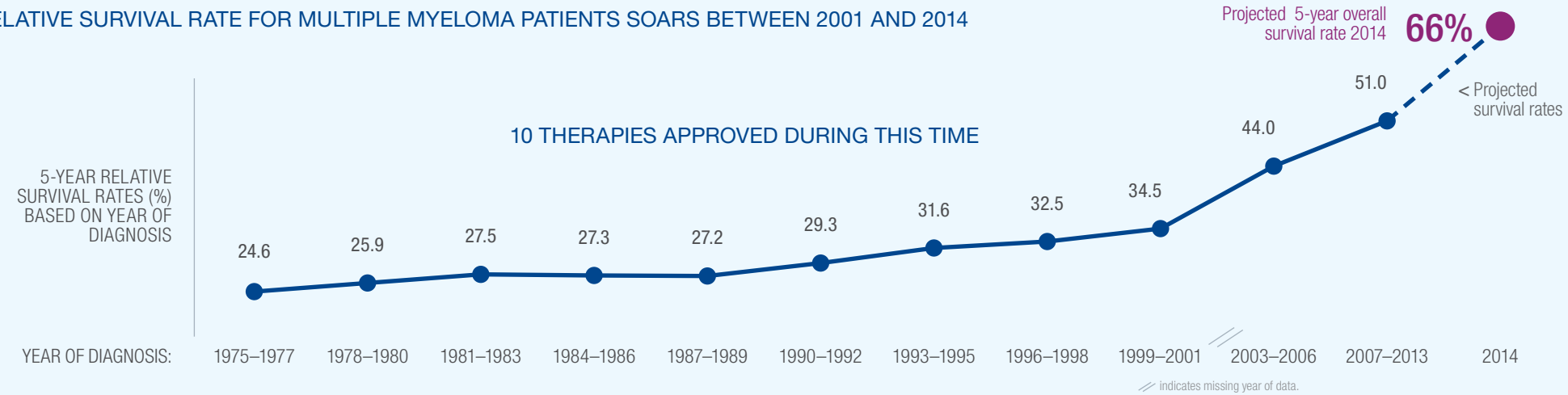
As the direct beneficiaries of Celgene's research and development efforts, patient needs inform the products we are bringing to market, with overall patient experience continuing to be a primary driver of innovation. We believe that value to patients is multi-dimensional and can be seen in three distinct ways:

1. Improvement in patient outcomes;
2. Improvement in patient quality of life; and
3. Provision of patient education and support.

The core focus of our R&D efforts is improving patient outcomes and, for some disease states, extending the lives of patients treated with Celgene products. Over the years, this dimension of value to the patient has been especially evident in multiple myeloma, where Celgene has played a lead role in bringing forward significant advancements in patient outcomes. For example, between 2001 and 2014, survival rates in multiple myeloma more than doubled. During that time period, multiple myeloma experienced a wave of innovation with significant investments in clinical trials and four new agents approved

**IMPROVED SURVIVAL IN MULTIPLE MYELOMA (2001–2014)[16]**

RELATIVE SURVIVAL RATE FOR MULTIPLE MYELOMA PATIENTS SOARS BETWEEN 2001 AND 2014



by the FDA, including Celgene's REVLIMID® (lenalidomide) in 2006.[17] Furthermore, 5-year survival rates for multiple myeloma from 1990-2013 have increased more than four times faster than for other cancers.[18]

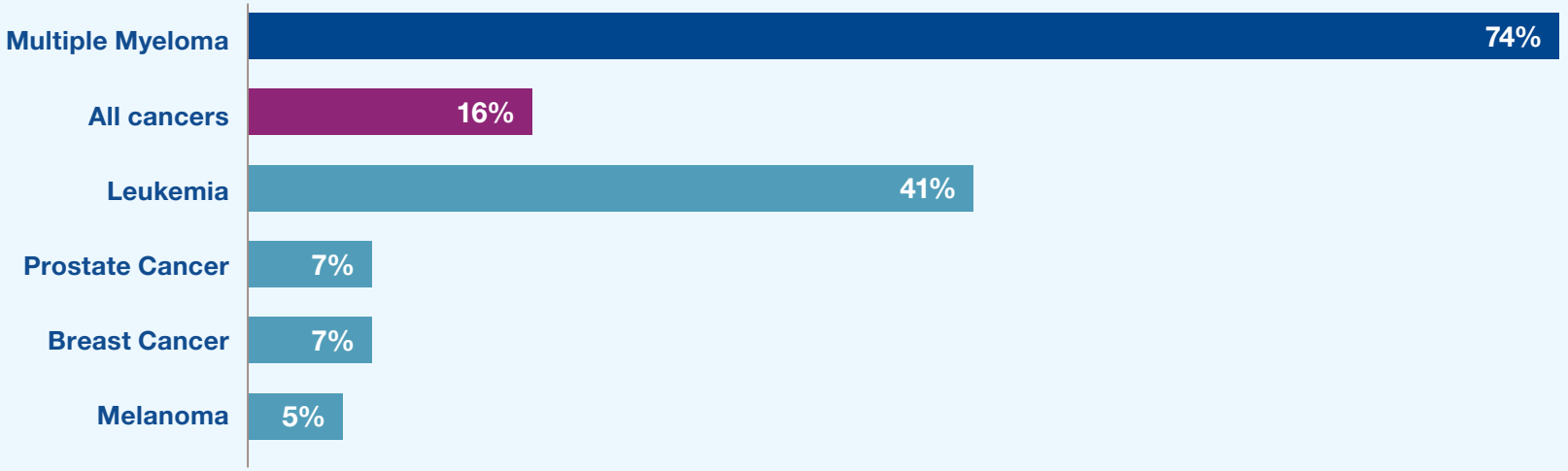
In newly diagnosed multiple myeloma patients who were not candidates for a stem cell transplant, continuous REVLIMID prolonged progression free survival (PFS) by approximately 4 months (primary endpoint) and prolonged overall survival (OS) by approximately 10 months (secondary endpoint) compared to melphalan, prednisone, and thalidomide (MPT).[19] Stated differently, REVLIMID continuously reduced the risk of death by 25 percent vs. MPT.[20] The improved patient outcomes offered by REVLIMID and other Celgene products are the result of considerable time and resources invested by Celgene over the years. It is only through these sustained and costly efforts that we have been able to impact patients' lives to such a great extent.

As patient outcomes improve, so should quality of life. This can mean patients being more available to spend time with family, return to a more active lifestyle, and generally feeling more like themselves again. For example, with OTEZLA® (apremilast), Celgene's treatment for moderate to severe plaque psoriasis (PSO) and adult patients with active psoriatic arthritis (PSA), over 70 percent of PSO patients in a pivotal study experienced a clinically meaningful improvement in quality of life as determined by the Dermatology Quality of Life Index.[21] The Dermatology Quality of Life Index assesses not only pain and discomfort, but also how the disease affects patients' confidence, relationships, and ability to engage in everyday activities.[22]

For many conditions, a return to seemingly mundane activities like shopping or gardening can boost patient morale and help change their outlook on life, to say nothing of the productivity that results from those patients who are able to return to the workplace as active contributors to the economy.

Recognizing that drug administration and adherence are important factors that can affect patient quality of life

**CHANGE IN 5-YEAR SURVIVAL RATES FROM 1990 - 2013[23]**



for many different disease states, Celgene continues to invest in the development of oral therapies. In certain conditions, some oral therapies have demonstrated a 40 percent reduction in the number of HCP visits and shorter appointments when compared to patients on injectable therapies.[24] For some patients, these are the types of details that can make the difference between being compliant and not consistently taking their medication.

In 2016, more than 500,000 patients were treated with Celgene medicines around the world. As part of Celgene's commitment to providing value to patients on multiple levels, we provide ongoing patient education and support to patients on Celgene treatments.[25] To date, more than 293,000 patients treated with Celgene's products have received patient support, including disease education and health-system navigation, through Celgene's patient support programs.[26] In addition to partnering with over 200 patient organizations to support and advance pro-patient policies, outreach, education and advocacy activities, Celgene is investing to make sure that the patient perspective is incorporated throughout research and development.[27] This includes hosting patient roundtables around topics such as CAR T and Crohn's disease, developing patient-reported outcomes and engaging patients in conducting unmet need assessments. We remain committed to supporting patients by not just developing cutting-edge therapies but also by addressing other potential barriers that can prevent patients from realizing the full benefits of our innovations.

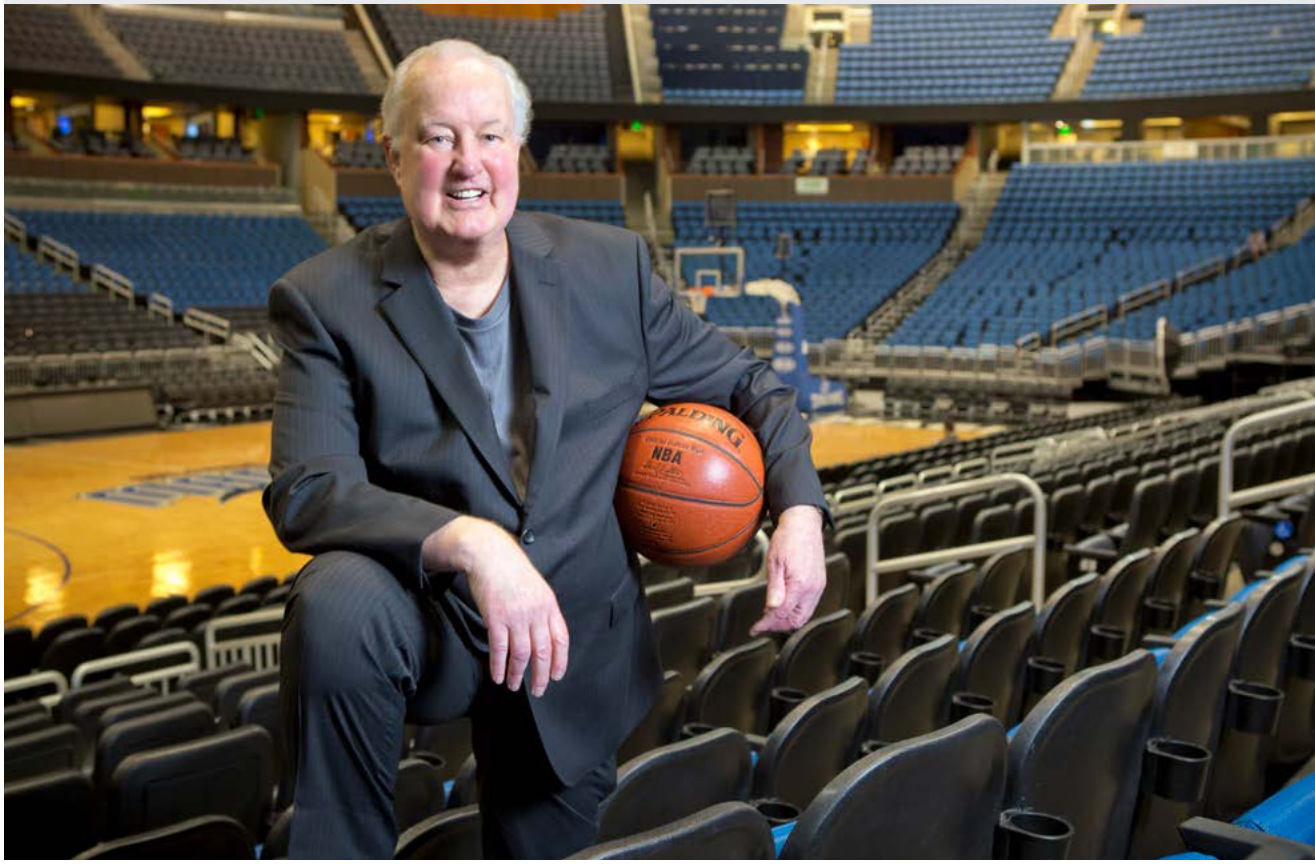
## BY THE NUMBERS: VALUE TO PATIENTS

**500,000**
patients treated with Celgene products in 2016[28]

**293,000+**
patients received support and education from Celgene[29]

**200+**
partnerships with patient organizations[30]

**74%**
increase in 5-year survival rate in multiple myeloma from 1990 to 2013[31]




***Pat Williams was diagnosed with multiple myeloma***

# Value to the Health System

*Thomas Goode was diagnosed with multiple myeloma*

# Value to the Health System

Due to the interconnected nature of the healthcare system, the value that Celgene provides does not stop at the patient. As a result, we are able to track the impact of our innovations throughout the healthcare system, representing considerable cost savings and further evidence for cultivating a health system that promotes and incentivizes medical innovations.

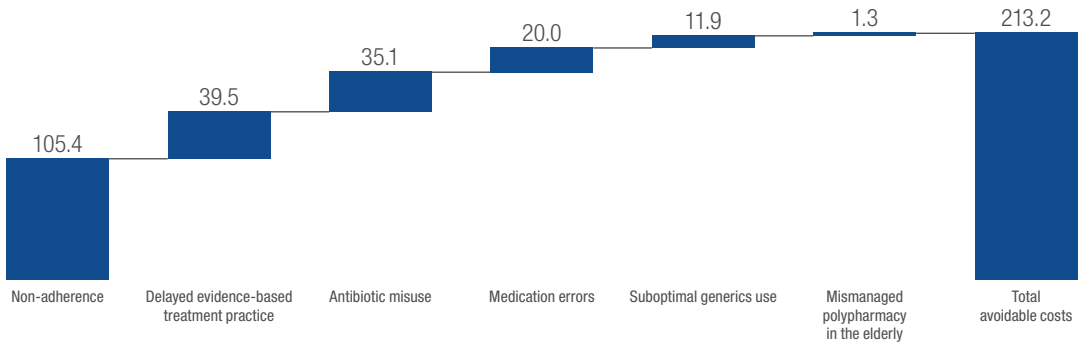
At Celgene, we define the value we provide to the health system as the following:

1. Reduction in spending on other medical services due to the better use of therapies;
2. Investment in academic research, investigator-initiated trials and real-world evidence; and
3. Support for physician education.

While total healthcare expenditure has seen constant growth globally, per-capita spending on medicines in OECD countries actually decreased by an average of 1.8% annually from 2005 to 2013.[32] This reality seems counter to the conventional wisdom that drug spending is at the root of the health spending woes that many countries are facing. Further supporting this point is that in the United States, biopharmaceutical innovation helps eliminate up to $213 billion in annual healthcare costs through supporting better use of medicines.[33]

**AVOIDABLE HEALTHCARE COSTS FROM BETTER USE OF MEDICINES[34]**

## BREAKDOWN OF ESTIMATED AVOIDABLE COSTS (US$BN, 2012)



In 2013, medical costs for oncology patients receiving treatment under the Medicare prescription drug program, Part D, were 58 percent lower than Congressional Budget Office medical cost estimates for this population ($17,831 vs $42,606).[35] Patients utilizing Part D only for their treatment used fewer inpatient services, outpatient services, and physician services.[36] This illustrates the ability for innovative products to significantly reduce downstream healthcare costs.

Celgene has actively sponsored academic and investigator-led trials across its portfolio to further contribute to research, which in turn benefits the healthcare system. As of March 2018, we are supporting 206 global investigator-led trials and cooperative groups (COOPs) in multiple myeloma alone.[37] As of June 2017, over 19,000 patients were enrolled in ongoing studies.[38]

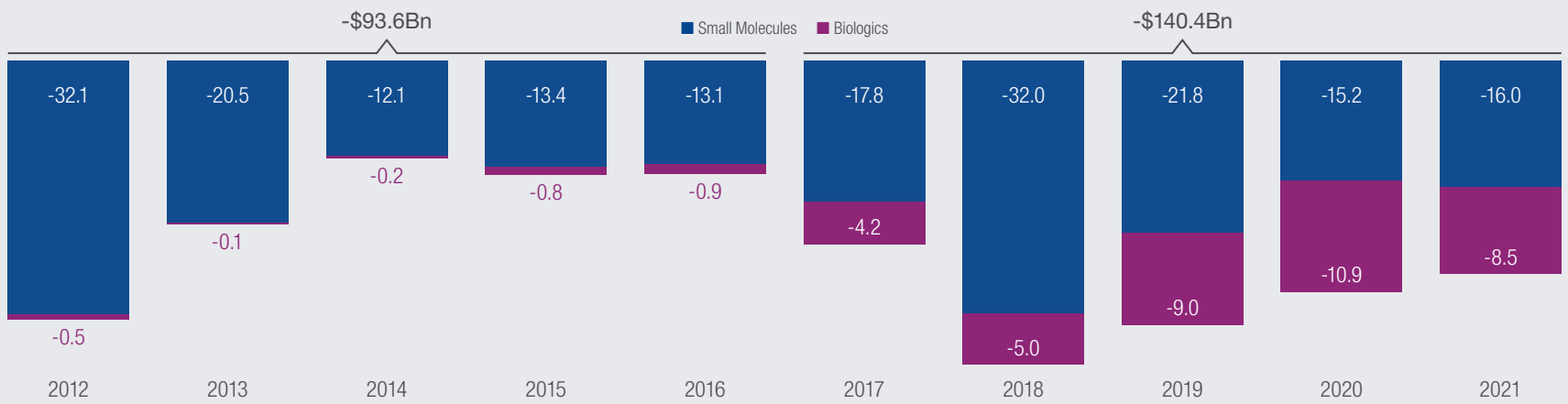
The healthcare provider community is an essential link between the development of innovative therapies and the patients who ultimately receive these products. In recognition of the integral role of healthcare providers, Celgene provides grants for independent and non-promotional scientific and physician education to improve disease awareness, understanding, diagnosis, and treatment.

As Celgene's products lose exclusivity, generic versions – products with the same value as the original brand product – are made available at reduced costs, thereby providing an everlasting benefit to the healthcare system. From 2012 to 2016, loss of exclusivity accounted for $93.6 billion in savings to the healthcare system.[39] In 2016 alone, generics accounted for 89.5% of total prescriptions dispensed in the United States.[40] When there are multiple generic versions of an approved product, market competition typically results in prices about 85% less than the brand-name drug.[41]

**SAVINGS TO THE HEALTHCARE SYSTEM FROM GENERICS[42]**

## ACCELERATIONS OF LOSS OF EXCLUSIVITY CONTINUE TO DRIVE SUBSTANTIAL PRICE DECREASES AND EXPECTED RESULTING SAVINGS IN THE NEXT 5 YEARS, INCLUDING BIOSIMILARS

The impact of patent expiries has been relatively unchanged for the past three years but is expected to increase sharply.



## BY THE NUMBERS: VALUE TO THE HEALTH SYSTEM

**$213 billion**

in annual healthcare costs eliminated through better use of medicines[43]

**206**

global investigator-led trials and cooperative groups in multiple myeloma[44]

**19,000+**

patients enrolled in ongoing studies[45]

The widespread use of generics, and the savings they represent, demonstrates the ability of Celgene's innovations to provide value to the healthcare system that extends well beyond a product's launch.

# Value to the Economy and Society

***Wendy Ryder was diagnosed with psoriatic arthritis***

# Value to the Economy and Society

For Celgene, our pursuit of innovation has a direct impact on the economy and society in which we operate. We've seen firsthand how our products, and the jobs that we create, can increase productivity and provide an important boon to the economy. We view this type of value as a combination of the following:

1. Increase in patient productivity;
2. Contribution to the local and national economy; and
3. Benefit to patients' caregivers and families.

Celgene's products have had a demonstrable impact on patient outcomes and quality of life which, in turn, can greatly impact patient productivity. For some patients, their improved condition can mean that they finally return to the workplace and resume their status as productive employees with incomes that are taxable. This undoubtedly leaves patients, employers and governments better off.

OTEZLA® is one such example of how Celgene's products can increase patient productivity; in one study it was observed that treatment with OTEZLA for adult patients with active psoriatic arthritis resulted in improvements in work productivity measured by physical, mental, time management, and output demands.[46]

The biopharmaceutical sector, including Celgene, provides an important stimulus to the U.S. economy through both direct and indirect contributions. In 2015, the biopharmaceutical sector supported $1.3 trillion in total output in the United States.[47] The sector also employed more than 800,000 workers and supported a total of 4.7 million jobs across the country.[48] The number of Celgene full-time employees has quadrupled over the last decade, creating thousands of high-quality jobs that includes more than 2,500 researchers.[49] These jobs have proven to be a significant benefit to the communities and local economies where we are engaged.

By improving patient outcomes, Celgene's products also impact the lives of patients' caregivers and family members. In 2015, it was estimated that 43.5 million caregivers provided unpaid care to an adult or child.[50] According to the AARP Policy Institute, in 2013, the value of unpaid caregiving was approximated to be $470 billion, exceeding the value of paid home care and total Medicaid spending in the same year.[51] In a disease state such as cancer, the requirements of caregivers and families are especially demanding – cancer caregivers spent an average of 32.9 hours a week caring for their loved one, with 32 percent providing 41 or more hours of care weekly, the equivalent of a full-time job.[52] For caregivers who are employed, this can have obvious implications for their job as 63 percent reported having to make a workplace accommodation as a result of caregiving.[53] By improving the lives of patients, Celgene is also helping to improve the lives of their caregivers.

## BUILDING A CAR T MANUFACTURING FACILITY IN SUMMIT, NJ

Celgene – as part of its investment in the development of CAR T therapies and the company's broader commitment to boosting the surrounding economy – has built a state-of-the-art cellular immunotherapy production facility in Summit, New Jersey. Unlike traditional pharmaceutical manufacturing facilities that manufacture large batches of chemical or biological products, CAR T therapies are highly personalized and each batch is manufactured for a specific patient using his or her own cells. While initially focused on CAR T, the facility's modular design will allow it to be adapted for the production of other cellular immunotherapies.

Phase I of the design, construction and commissioning of the new Summit production facility was completed in just nine months; this phase involved some 800 external contractors from U.S. engineering and construction firms who worked in collaboration with Celgene staff to ensure an accelerated delivery on the project.[54]

The new facility in Summit is projected to create hundreds of new jobs in the next three years. The commitment of financial resources and the anticipated new hires are clear indicators of the value that Celgene provides to the patients we serve, and to our local, state and national economies.

## BY THE NUMBERS: VALUE TO THE ECONOMY AND SOCIETY

**$1.3 trillion**

total output by the biopharmaceutical sector in the U.S. in 2015[55]

**800,000+**

U.S. workers directly employed by the biopharmaceutical sector in 2015[56]

**4.7 million**

total jobs in the U.S. supported by the biopharmaceutical sector in 2015[57]

**2,500+**

researchers added to the Celgene workforce over the last ten years[58]

**800** external contractors from U.S. engineering and construction firms designed and constructed Celgene's new CAR T facility in Summit, NJ[59]

***Susan Freeman was diagnosed with plaque psoriasis***

# Value to Future Innovation

# Value to Future Innovation

At Celgene, today's innovations are important, but ensuring future breakthroughs is equally important. Patients remind us daily that fighting to address unmet medical needs must be our priority. That means we must continue to invest in tomorrow's technologies, and we must preserve the incentives that make such investments possible.

This viewpoint is encapsulated by our fourth value pillar – the value to future innovation – which we at Celgene define as:

1. Investment in discoveries about existing medications and new therapies;
2. Investment in medical innovation for significant patient medical need; and
3. Contribution to the development of a competitive but collaborative medical ecosystem.

Celgene prides itself in being, first and foremost, an R&D company. We take our commitment to science seriously. We continually reinvest revenue from drugs currently on the market towards developing new therapies that can improve patient outcomes. In 2016, Celgene reinvested 39.8 percent of its revenue into R&D, the third highest of the 2,500 companies investing the largest sums of R&D in the world – including aerospace and defense, automobiles and other transport, chemicals, health industries, ICT sectors and industrials.[60] In 2017, that number increased to 45.5 percent, almost 15 percent more than any other top biopharmaceutical company.[61] For 2017, this translated to Celgene spending more than twice on R&D than sales and marketing.[62]

We believe that relentless innovation is good for both patients and Celgene. Indeed, our company's mission revolves around the idea that today's investments are tomorrow's cures, and the best way to eliminate healthcare costs associated with a disease is to find the cure.

## A SECOND LIFE BY PARTICIPATING IN A CLINICAL TRIAL FOR AN INNOVATIVE AML THERAPY

When Ralph Hills was diagnosed with an aggressive blood cancer called acute myeloid leukemia (AML), his doctor told him to get his affairs in order. He interpreted that statement as a polite way of saying that he didn't have long to live. But a last-minute phone call from the doctor led him to participate in a clinical trial for his disease.

"The night before my chemotherapy was going to start, my doctor called during her ski vacation. She asked me if I would consider changing my treatment plan. Apparently, I had a molecular mutation in a gene that might respond to a targeted therapy that was in clinical trials. So, I had a choice of being treated with chemotherapy or an unknown treatment. I trusted my doctor and knew that she wouldn't have offered it to me unless she thought it was the right treatment for me at that time."

Ralph Hills had an isocitrate dehydrogenase-2 (IDH2) mutation and enrolled in a clinical trial for IDHIFA® (enasidenib). For six months, he continued to battle the effects of AML, leaving him unable to eat regular food and with limited mobility. He lost 45 pounds. Then, he began to notice a considerable change as his levels of leukemia cells began to consistently drop, ultimately resulting in indiscernible leukemia.

Says Hills, "That moment was the start of my second life."

Based on the results of the clinical trial in which Ralph participated, Celgene submitted and received FDA approval for IDHIFA as a treatment for relapsed or refractory AML patients with an isocitrate dehydrogenase-2 (IDH2) mutation as detected by an FDA-approved test. IDHIFA is the first and only FDA-approved therapy for patients with R/R AML and an IDH2 mutation, which represents between 8 and 19 percent of AML patients. This milestone reflects the value that investment in innovative research brings to patients.


Celgene and its peers in the biopharmaceutical sector take on significant financial risk in the research and development of products that, more likely than not, will never even make it out of clinical trials. Having witnessed the benefits that approved medicines can bring to patients, the health system, and society, Celgene willingly accepts this risk as a core part of its business model.

For us, future innovation means targeting areas with high patient and scientific unmet need. Instead of developing treatments that represent incremental improvements over current standards of care, we are looking to take on diseases where, many times, patients are faced with limited options. And we're willing to spend to do it: we spent $4.5 billion on research in 2016, nearly as much as the National Cancer Institute.[63] That allowed us to advance nine novel therapies – and 19 pivotal trials – in hematology/oncology and inflammation/immunology.[64]

Celgene is as active as ever in R&D. Since the first approval of REVLIMID® in 2006, Celgene has invested another $20 billion in R&D. And Celgene is expanding into new disease states as evidenced by its growing pipeline of therapies for immune and inflammatory disorders such as multiple sclerosis, ulcerative colitis, Behçet's disease and Crohn's disease. As of June 2017, Celgene was sponsoring 231 clinical trials for 33 unique compounds.[65] Of these, 22 were pivotal phase III clinical trial programs.[66]

These ambitions do not come without a price. For every REVLIMID, POMALYST® and OTEZLA®, there are countless compounds that do not make it out of clinical trials despite significant time and financial investments. Still, Celgene continues to engage in the high-stakes pursuit of tomorrow's cures in the hope that some of its compounds will reach the market, thereby providing value to patients, the healthcare system and broader society.

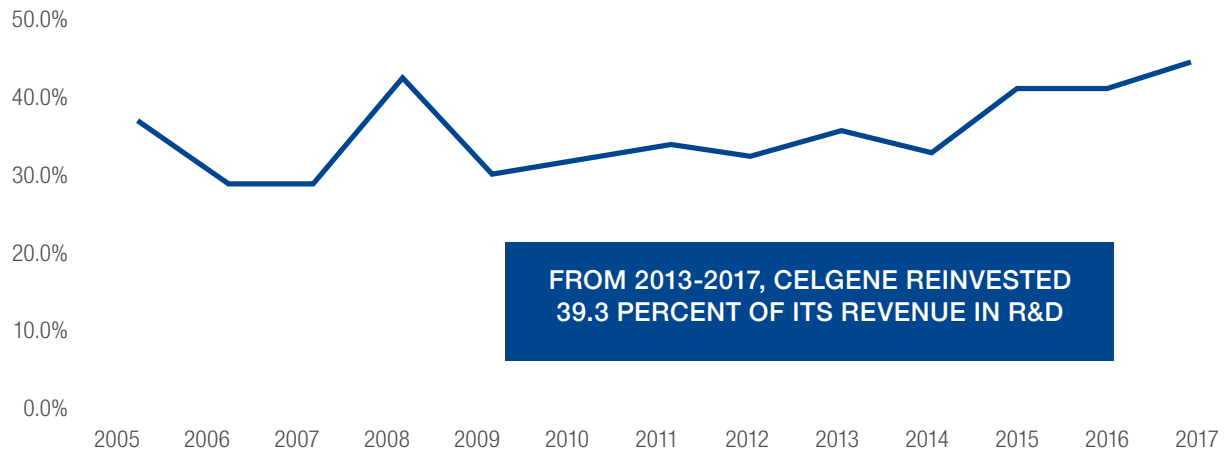
Celgene also believes that innovation means finding new ways that already-developed therapies can benefit patients. It is in this spirit that we continue to explore new indications and generate additional clinical data for proven treatments such as REVLIMID and OTEZLA.

Celgene believes that a competitive and collaborative medical ecosystem is necessary to enable and incentivize future innovation. In the pursuit of innovation, the whole is greater than the sum of its parts. This has been especially evident in multiple myeloma, where four of the five novel agents launched since 2013 have been approved for use in combination with REVLIMID.[67]

There is perhaps no better example of Celgene's competitive and collaborative spirit than its recent efforts in CAR T, considered by many to be the next frontier in cancer therapy. Recognizing the immense potential for

**CELGENE'S R&D INVESTMENT OVER THE YEARS[68]**

## CELGENE R&D SPENDING OVER TIME AS A PROPORTION OF REVENUES SINCE 2005 %



CAR T, Celgene has adopted a multipronged strategy for advancing the development of these potentially transformative therapies for patients with incurable blood cancers. In January 2018, Celgene announced its acquisition of Juno Therapeutics, a pioneer in the development of CAR T therapies. The acquisition of Juno is in addition to Celgene's ongoing partnership with bluebird bio to navigate the new frontier of CAR T, which poses not only a scientific challenge, but a logistical, manufacturing and economic challenge as well. Such an endeavor requires the exact assets Celgene has worked to develop: scientific expertise, manufacturing excellence, and imagination, helping to make us a partner of choice.

Our collaboration with bluebird bio is just one example of many – Celgene is currently supporting over 30 collaborative business development partnerships.[69] Among these partnerships are collaborations with upstart biotechs, academic medical centers and established pharmaceutical companies, all in the name of developing the transformative therapies of tomorrow.

## BY THE NUMBERS: THE RISK OF DRUG DEVELOPMENT

**10 to 15 years**
average time it takes for a medicine to make its way through the entire R&D process to FDA approval[70]

**9.6 percent**
of investigative medicines entering clinical trials are ultimately approved by the FDA[71]

**5 in 5,000**
compounds that enter preclinical testing advance to human testing[72]

**1 of 5**
compounds tested in people is approved by the FDA[73]

**2 in 10**
FDA-approved medicines produce revenues that exceed average investment[74]

**5.1 percent**
likelihood of approval for investigative medicines in oncology[75]

**$2.6 billion**
average cost to develop a new medicine, including the cost of failures[76]

**> 7,000**
medicines in development globally[77]

Ensuring the future of innovation means not only partnering with other research organizations, but also engaging payors, providers and patients to incorporate perspectives from throughout the broader healthcare system. We are constantly exploring potential collaborative opportunities that can enhance access to our therapies and ultimately improve patient outcomes. It is only through these types of partnerships that our health system will be able to evolve in a way that continues to foster innovation. The siloes must be broken down, data must be shared, and competitive advantages must be exploited so that patients, the health system and the broader economy can continue to reap the rewards that Celgene and its peers are able to offer through their commitment to innovation.

## CELGENE'S R&D NETWORK

**Celgene has R&D facilities located strategically throughout the United States and Europe that are uniquely equipped for a specialized approach to the company's pursuit of innovation.**

The facility in **Cambridge, Massachusetts** serves as the Immunology and Inflammation Thematic Center of Excellence.

The Drug Discovery and Alliance Development Center in **San Diego, California** includes the Protein Homeostasis Thematic Center of Excellence and the Epigenetics Thematic Center of Excellence.

The Translational Development Center in **San Francisco, California** is the main site for Celgene's oncology early development and biomarker research.

The facilities in **Seattle, Washington** provide support for Celgene's CAR T programs as well as for the Immuno-Oncology Therapeutic Center of Excellence.

**Seville, Spain** is home to the Celgene Institute for Translational Research Europe (CITRE).

**The Summit, New Jersey** location houses Celgene's pharmaceutical and biologics development laboratories as well as pilot plants for early stage cGMP manufacturing. The site also includes a cutting-edge facility for manufacturing of CAR T and other cellular immunotherapy products.

## WHAT IS CAR T?

**Q: What is the underlying science of CAR T therapies?**

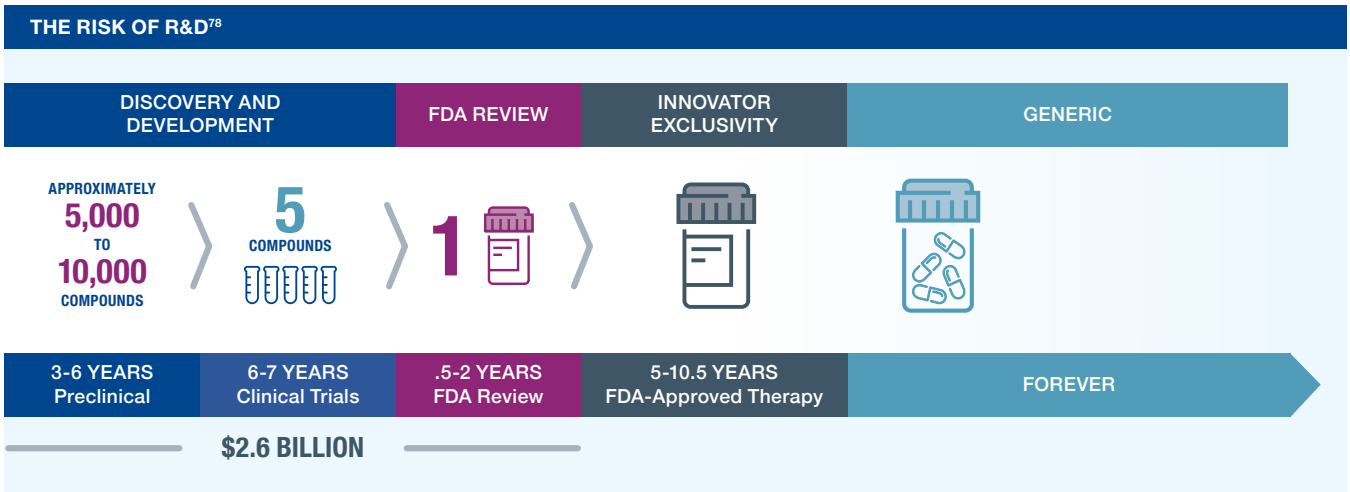
A: CAR T therapies seek to enhance a patient's own T cells with the goal of targeting antigens and killing tumor cells associated with certain cancers. The science is evolving through further focus on both how these products are made and how patients respond to treatment. Celgene is at the forefront of this work and will continue to advance the area of cell and gene therapy. Celgene's CAR T therapies are investigational and have not been approved by the FDA.

**Q: How does Celgene's focus on CAR T demonstrate the company's commitment to patients? The healthcare system? Broader society?**

A: Celgene's focus in cancer has always been to provide game-changing therapies that will help patients. Science is evolving and CAR T therapy will play a large role in how we battle cancer both now and in the future. Patients who had little hope previously because they exhausted available treatments may have alternative options through the advancement of research into CAR T therapies like liso-cel and bb2121.

**Q: What is required of the healthcare system to sustain and scale the use of CAR T therapies?**

A: With personalized treatments like CAR T that may require only a single administration, traditional payment models may not be appropriate. The healthcare system therefore needs to explore innovative payment models that can continue to incentivize the development of innovative therapies like CAR T. Celgene will work with health authorities across the globe to ensure that there is a shared view of the value of CAR T therapies.



## BY THE NUMBERS: CELGENE INNOVATION

**45.5%**
of 2017 revenue reinvested in R&D by Celgene[79]

**$4.5 billion**
spent by Celgene on research in 2016[80]

**2x**
as much Celgene spending on R&D than sales and marketing in 2017[81]

**$20 billion**
invested in R&D since the first approval of REVLIMID® in 2006[82]

**30+**
collaborative business development partnerships supported by Celgene[83]

**231**
clinical trials currently sponsored by Celgene[84]

**33**
unique compounds being examined in clinical trials[85]

**22**
pivotal/phase III programs currently underway[86]

### CELGENE'S PARTNERSHIPS ACROSS THE HEALTHCARE ECOSYSTEM[87]

ABIDE THERAPEUTICS · Columbia University Medical Center · Adimab · NIMBUS THERAPEUTICS · agios · Mount Sinai · bluebirdbio · ACCELERON · AnaptysBio · Johns Hopkins University · Sanford Burnham Medical Research Institute · CoNCERT Pharmaceuticals Inc. · blue line BIOSCIENCE · gemoab MONOCLONALS GMBH · Epizyme · BeiGene · evotec · Penn Medicine · AstraZeneca · Ligand · Jounce THERAPEUTICS · FORMA THERAPEUTICS · MOFFITT CANCER CENTER · Inception IBD · nurix · OncoMed PHARMACEUTICALS · ANOKION · NantBioscience · Recombinant Antibody Network · nografpharma · Northern Biologics · SUTRO BIOPHARMA · MedImmune · Bristol-Myers Squibb · triPHASE · HIGHLINE therapeutics · zymeworks · abbvie

# Conclusion

***David Clark was diagnosed with psoriatic arthritis***

# Conclusion

## The conversation around value is not static, and we must continually assess the value we provide patients, the healthcare system and society in light of the four pillars to ensure that we are meeting our commitment as innovators.

This report will not be our final word in the policy debate on value, and we will judge ourselves going forward on the metrics we have outlined. We will continue striving to be industry leaders in understanding the impact of our products on not only the health status of our patients, but their ability to live full and productive lives. We will remain rigorous in our efforts to quantify health system savings related to the innovations that we bring to market. We will leverage our endless pursuit of innovation as a way to strengthen the economies in which we operate. And we will use reinvestment in R&D as a yardstick of our commitment to future innovation.

*Emma Hochreiter was diagnosed with acute myeloid leukemia*

*Phil Falkowitz was diagnosed with multiple myeloma*

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***Kara Errington was diagnosed with plaque psoriasis***

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