



Statement of

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before the

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Chairwoman Maloney, Ranking Member Comer, and Members of the Committee, thank you for the opportunity to be here today to discuss Bristol Myers Squibb, our acquisition of Celgene Corporation, and our focus on developing the next generation of therapies for patients' unmet medical needs. As a physician myself, I want you to know that I share your concerns about the cost of prescription medications for patients, especially in the context of an ongoing global pandemic. I believe that it is our collective responsibility to ensure that patients have access to the medicines they need, and I applaud the Committee for examining this important public policy and public health issue.

The COVID-19 pandemic has brought the issues of health care costs and drug pricing, patient access, and scientific innovation into even sharper focus. Bristol Myers Squibb is seeking to do our part to support efforts to combat COVID-19 and mitigate the pandemic's impact on patients and families. Although antiviral medicines are not our area of specialty, we are using our expertise in immunology to evaluate compounds that might have an impact on the inflammatory immune response associated with COVID-19, and we are working with the broader life sciences community to brainstorm ways that stakeholders can collaborate to accelerate the development, manufacturing, and delivery of vaccines, diagnostics, and treatments for COVID-19. In addition, we recognize that many businesses have closed and many people have lost their jobs and health insurance coverage during this pandemic. Because of this, we have expanded the eligibility of our existing patient support programs to include certain patients who are unemployed and uninsured due to the pandemic. The Bristol Myers Squibb Company and Foundation are also contributing to global relief efforts. By the end of last month, Bristol Myers Squibb's COVID relief contributions totaled more than \$33 million in financial support, medical equipment, and personal protective equipment, across 45 countries. Although the pandemic has been devastating to millions, I have been heartened by the industry's efforts to provide relief for patients who need it and innovation to help people continue to live longer, healthier lives.

More than thirty years ago, I joined the biopharmaceutical industry because I saw the very real difference that pharmaceutical innovation can make in people's lives. I am exceptionally proud of Bristol Myers Squibb's 130-year history of improving outcomes for patients. Our research has contributed to the development of medicines that have reduced

mortality for cardiovascular disease and helped to transform HIV/AIDS from a death sentence into a chronic disease.

Over the past several decades, medical innovations have made dramatic improvements in the treatment of cancers. Bristol Myers Squibb has been a pioneer in the field of immuno-oncology through the development of two medicines, Yervoy and Opdivo, that have transformed survival expectations for many patients with cancer. As one example, prior to the availability of modern immuno-oncology treatments, only 25% of patients diagnosed with metastatic melanoma survived a year. Today, thanks to immuno-oncology therapies, the one-year survival rate has increased threefold to 74%.

Through our continued investments in research, we are now on the cusp of a new generation of treatments that harness the power of the body's own immune system to treat cancers. This year, the Food and Drug Administration accepted and granted priority review to our applications for lisocabtagene maraleucel (liso-cel) and idecabtagene vicleucel (ide-cel), two new chimeric antigen receptor T cell therapies (CAR-T) that will treat patients with advanced stages of large B-cell lymphoma (the most common and aggressive form of non-Hodgkin lymphoma) and multiple myeloma, respectively. These are patients that have failed to respond to multiple existing therapies, and have few options available. CAR-T therapies are truly modern miracles. Through genetic engineering, we are now able to create T cells that target specific proteins in cancer cells, enlisting the body's natural immune system in the defeat of cancer.

We have seen similar extraordinary gains in the prognosis of patients with multiple myeloma, the blood cancer that is treated by Revlimid, a drug that was developed by Celgene. Multiple myeloma is a very serious cancer that causes cells to accumulate in the bone marrow, where they crowd out healthy blood cells. Experts estimate that this year, more than 32,000 Americans will be diagnosed with new cases of multiple myeloma, and more than 12,000 people will perish from this devastating disease.

Nonetheless, the prognosis for a multiple myeloma patient today is far better than it was just a few years ago. According to the National Cancer Institute's Surveillance, Epidemiology, and End Results (SEER) data, the five-year relative survival rate for multiple myeloma patients has doubled, from 27% to 54%, over the past twenty-five years. The advances in multiple myeloma treatments are especially noteworthy when compared to other cancers: the five-year survival rates for multiple myeloma increased four times faster than for other cancers. Revlimid, which was approved about fifteen years ago, is one of the most significant contributors to these survival rates. Today, Revlimid is the backbone therapy for multiple myeloma treatment, and the benefits of Revlimid continue to be explored. Further research and development in multiple myeloma treatments has given us other new therapies, such as Pomalyst, which the FDA approved seven years ago.

Significant and sustained investment in research and development by Celgene resulted in a robust pipeline of new products. This pipeline, along with its extensive research capabilities, was the primary factor in Bristol Myers Squibb's decision to pursue an acquisition of Celgene. Celgene's substantial near-term pipeline of products will now benefit from Bristol Myers Squibb's larger scale and existing experience in oncology and immunology. These include

treatments for myelofibrosis (Inrebic), multiple sclerosis (Zeposia), anemia in patients with myelodysplastic syndrome (Reblozyl), non-Hodgkin lymphoma (liso-cel), multiple myeloma (ide-cel), and acute myeloid leukemia (Onureg). We already achieved the launches of Inrebic, Reblozyl, Zeposia and Onureg. Additionally, the FDA has accepted our submissions for liso-cel and ide-cel this year, and granted priority review for both. Celgene also had a strong early-stage pipeline that is being integrated into Bristol Myers Squibb's broader research efforts. In total, Bristol Myers Squibb now has more than fifty compounds in active development, covering more than forty different disease areas. We are also evaluating compounds that may have an impact on the inflammatory immune response associated with COVID-19.

Both Celgene and Bristol Myers Squibb have exceptionally strong records of devoting substantial portions of our overall revenue to research and development. According to the 2019 EU Industrial Research and Development Scoreboard, which ranks the top companies in the world by R&D spending, of the 50 companies globally with the most R&D spending, in any industry, Celgene was ranked first and Bristol Myers Squibb was ranked second for R&D spending as a share of revenue. As a combined company this year, we expect to invest nearly \$10 billion in research and development. A complete chart of our pipeline is attached to my testimony.

Development of Revlimid

Celgene's invention of Revlimid began in the 1990s with the company's research into thalidomide as a possible treatment for HIV and AIDS. Thalidomide, as many of you will remember, brought about one of the darkest episodes in modern medicine. Sold by other companies without a thorough understanding of its teratogenic side effects, thalidomide caused thousands of infant deaths and led to a generation of babies born with severe birth defects. Because thalidomide was an infamously dangerous molecule, many companies were unwilling to devote resources to its research and development. Celgene, however, was spurred by the AIDS epidemic to take on these risks and challenges in the hope that it could turn a dangerous molecule into something beneficial for patients struggling with HIV/AIDS.

Given thalidomide's history, Celgene's early research focused on identifying potential alternatives to thalidomide that might have improved safety profiles or be more effective in treating other conditions. Over fourteen years, Celgene's researchers created and tested hundreds of proprietary small-molecule compounds to look for alternatives to thalidomide. During that period, Celgene invested more than \$800 million in research and development. Because thalidomide's method of action was unknown at that time, the research process was trial and error. Scientists synthesized, tested, and analyzed various compounds and—if one proved promising—they would pursue preclinical studies and eventually clinical trials. The process was time consuming, laborious, and very expensive. Moreover, there was absolutely no guarantee that any of the compounds that were developed and tested would have any benefit over thalidomide.

Ultimately, Celgene's extensive research efforts led to the promising invention of Revlimid. Following this discovery, Revlimid underwent rigorous testing before its initial approval in 2005, including 34 nonclinical pharmacology studies; 15 nonclinical pharmacokinetic studies; 25 toxicology studies; numerous pharmaceutical substance and product

manufacturing studies; analytical methods development, quality control and stability testing; 6 clinical pharmacokinetic studies; and 3 clinical trials in myelodysplastic syndrome patients.

Following approval, Celgene continued to invest in Revlimid research, including more than 50 Celgene-sponsored clinical studies, encompassing multiple myeloma, non-Hodgkin lymphoma, mantle cell and other lymphomas, chronic lymphocytic leukemia, acute myeloid leukemia, and multiple solid tumor cancers. This research and development resulted in FDA approvals for additional indications for Revlimid, including numerous approvals in multiple myeloma, mantle cell lymphoma, follicular lymphoma, and previously treated marginal zone lymphoma. As with all pharmaceutical research, Celgene also invested in promising prospects that ultimately proved unsuccessful, including research into prostate cancer, non-deletion 5q myelodysplastic syndromes, and certain forms of lymphoma. Overall, Celgene invested more than \$31 billion in research and development since it began research into thalidomide.

Given the history of thalidomide, Celgene worked closely with the FDA to develop a comprehensive risk evaluation and mitigation strategy (“REMS”). The FDA’s decision to consider approving thalidomide for the U.S. market was controversial, and the FDA conditioned Celgene’s approval on the development and implementation of rigorous distribution restrictions. Although Revlimid has a better safety profile than thalidomide, it also has significant teratogenic risks, and it is therefore subject to similar restrictions. Revlimid’s REMS program ensures that doctors, patients, pharmacists, and others are handling Revlimid with the care that it warrants. These programs have been incredibly important to protecting patients. Gratifyingly, there have been no reports of children born with birth defects as a result of Celgene’s products since they were introduced. Importantly, Celgene also prioritized safety when providing generic manufacturers with access to Revlimid. Celgene provided samples to generic manufacturers subject to controls designed to protect patient safety.

Pricing and Access

We believe that drug pricing should be considered in the context of the value, or benefit, the medicine delivers to patients, healthcare systems, and society overall. As such, at Bristol Myers Squibb, we price our medicines based on a number of factors, including, among others, the value of scientific innovation for patients and society in the context of overall healthcare spending; economic factors in relation to the healthcare systems’ capacity to provide appropriate, rapid, and sustainable access to patients; and the ability to sustain our research and development investment in new innovations that address serious unmet medical needs.

For example, one of our products is Eliquis, an oral medicine that inhibits a key blood-clotting protein. Over the past few years, Eliquis has become the standard of care for decreasing blood clot formation in patients and it is prescribed millions of times each year. Eliquis can lower the risk of a stroke and prevent deep vein thrombosis and embolism, and it is commonly used to prevent blood clots following certain surgeries. Because Eliquis can help prevent very serious medical conditions that require hospitalization or other expensive medical treatments, numerous studies have demonstrated that Eliquis provides substantial savings to our healthcare system. Without the benefits of Eliquis, many patients would have substantially worse medical outcomes and the healthcare system would face dramatically higher costs.

With a product like Revlimid, which is extending the lives of patients with serious blood cancers, the value to patients is truly immeasurable. It is impossible, of course, to place a monetary value on years of additional life, and we therefore believe that patients who can benefit from our medicines should have access to them, regardless of their financial ability. For that reason, both Bristol Myers Squibb and Celgene have invested in robust patient assistance programs for a number of our drugs.

Although patient assistance programs are an imperfect solution to addressing our nation's drug pricing and access challenges, I am proud of the support Bristol Myers Squibb and Celgene have provided to patients who need it. For example, between 2007 and 2019, Celgene provided assistance to almost 160,000 patients receiving Celgene's hematology and oncology medicines. Between 2015 and 2019, Celgene provided more than \$1.97 billion of commercial copay assistance and free medicines. In 2019 alone, Celgene provided assistance to more than 8,000 Revlimid patients, including approximately \$18 million in copay assistance and more than \$482 million in free Revlimid. This year, we have helped even more patients gain affordable access to Revlimid. In the first eight months of 2020, we provided assistance to approximately 14,000 Revlimid patients, including more than \$21 million in copay assistance and nearly \$327 million in free Revlimid. Because we recognize that the COVID-19 pandemic may impact some patients' ability to access their medications, Bristol Myers Squibb also made the decision to expand eligibility for patient assistance for Bristol Myers Squibb and Celgene medicines.

Moreover, both Celgene and Bristol Myers Squibb have separately provided support to independent foundations that can provide financial support to patients insured by federal healthcare programs. Between 2015 and 2019, Celgene and Bristol Myers Squibb collectively donated more than \$1.2 billion to these foundations.

Because we embrace our broader social responsibility, Bristol Myers Squibb also supports the Bristol Myers Squibb Foundation, one of the largest foundations in the United States. An independent organization, the Bristol Myers Squibb Foundation promotes health equity and improved health outcomes for populations disproportionately affected by serious diseases. For example, African-Americans are twice as likely as other multiple myeloma patients to die from the disease. In addition to addressing the disparities in multiple myeloma treatment, the Foundation also provides support for improved and increased access to care, quality of care, and health outcomes for underserved populations, including individuals with low income, racial and ethnic minorities, and people in underserved areas.

Again, we recognize that patient assistance programs and foundations are an imperfect solution to addressing our nation's drug pricing and access challenges. The current system is replete with complexities, attributes, and incentives that undermine our efforts to make sure patients receive the medicines that they need. The current system often frustrates our ability to improve patient access by imposing barriers such as complex rebates, intermediary PBMs, increasingly high copays and deductibles, and federal rules that restrict our ability to assist patients in federal healthcare programs.

I welcome the opportunity to work with you and others to address these and other inadequacies in our healthcare system. Most critically, we need reforms that ensure that health insurance works as it is intended by spreading risks and costs across a large pool of insured

individuals. It is simply unacceptable that individual patients—even those with strong insurance coverage—are too often required to bear a disproportionate burden through high out-of-pocket expenses at the very time they most need the support of their insurance providers.

To address rising out-of-pocket expenses, we support reforms of the rebate system to focus on the best interests of patients. We also support efforts to ensure generic drugs are made available more quickly and more broadly when possible. Generic entry is an essential corollary to our system of promoting medical innovation through the patent system's period of exclusivity. We applaud the Administration's success with speeding the approval of generics, and supported the important improvements that Congress achieved with the passage of the CREATES Act. Finally, we support pricing innovations, such as value-based purchasing arrangements that tie payments to value. These models can reduce costs, improve access and adherence, and, most importantly, contribute to better outcomes. We support the efforts by the Department of Health and Human Services to remove regulatory barriers and facilitate greater use of these arrangements.

We believe that policymakers should closely guard the United States' policies that support innovation. These policies encourage innovators to take big risks and invest significant sums by safeguarding a return on those efforts for a reasonable period of time. This helps to fund our work on the next discovery that might alleviate pain or extend life. These policies are the reason that the United States leads the world in medical inventions and making new therapies available to patients.

Madam Chairwoman, thank you for the opportunity to be here today. I am very proud to be part of this historic era of biomedical innovation. It is incumbent on all of us to make sure that these innovations are available to the patients that need them. On behalf of my colleagues at Bristol Myers Squibb, and the patients we serve, I look forward to working together to implement real change that broadens access to innovative medicines for patients.