

Statement of Mark J. Alles
Former Chairman and CEO of Celgene Corporation

before the

Committee on Oversight and Reform
United States House of Representatives

September 30, 2020

Chairwoman Maloney, Ranking Member Comer, and Members of the Committee: Thank you for the opportunity to discuss Revlimid[®], a life-extending medicine approved by the FDA for the treatment of rare and incurable blood cancers.

My name is Mark Alles, and I have had the privilege of being part of the research-based pharmaceutical industry for more than 30 years. Before I joined this industry, I served in the Marine Corps and Marine Corps Reserve, and before that I taught junior high school. I have strived to bring the values of integrity, service and respect to every part of my career.

Revlimid was discovered, developed and brought to patients by my former employer, Celgene Corporation. Based in Summit, New Jersey, Celgene was a global biopharmaceutical company that specialized in the discovery, manufacturing, clinical development and delivery of innovative medicines for the treatment of cancer and serious inflammatory diseases.

I joined Celgene in 2004, and after serving in multiple different roles in the company, I was appointed as Chief Executive Officer in 2016 and Chairman of the Board in 2018. My last day with Celgene was December 2, 2019, after Celgene was acquired by Bristol Myers Squibb in November 2019. At that time, the company employed more than 8,000 people worldwide with approximately 5,600 employees in the United States.

One of the most clinically important therapies discovered by Celgene is the novel medicine lenalidomide, marketed as Revlimid. Revlimid's primary use is for the treatment of multiple myeloma – a rare and incurable blood cancer. Celgene invested approximately \$800 million over 14 years to invent and develop Revlimid before its first FDA approved use in late 2005. Revlimid is a unique, patented molecule that required a completely independent development program and a full FDA approval process. Revlimid has become a standard of care for the treatment of myeloma based on several large clinical studies that have demonstrated significant patient benefits.

Since Revlimid's initial FDA approval, the company continued to invest several hundred million dollars into the research and development of this medicine. At the time it was acquired, Celgene had, and was sponsoring, more than 50 additional Revlimid clinical studies for patients with different types of cancer. As is common in drug development, many studies did not succeed. However, several of these studies were successful and resulted in six additional FDA

approvals – including the most recent in 2019. Since 2005, more than 700,000 patients have been treated with Revlimid worldwide.

At Celgene, pricing decisions for our medicines were guided by a set of long-held principles that reflected our commitment to patient access, the value of a medicine to patients and the health care system, the continuous effort to discover new medicines and new uses for existing medicines, and the need for financial flexibility. In 2018, the company publicly committed to full pricing transparency by limiting price increases to no more than once per year, and at a level not greater than the Centers for Medicare and Medicaid Services' (CMS) projected increase in National Health Care Expenditures for the year, absent exceptional circumstances.

To help ensure patient access to our medicines, the company's Patient Support programs provided copay assistance to eligible, commercially insured patients, and provided free medicine to eligible patients. More than 140,000 people in the United States prescribed a Celgene cancer medicine received some form of assistance.

Celgene sold and offered to sell samples of its patented medicines to generic manufacturers, so long as those companies met critically important safety standards. These requirements were established to protect the public from the risks of severe birth defects associated with the known and suspected teratogenicity of some of its products – including Revlimid. In fact, multiple generic versions of Revlimid are licensed to enter the U.S. market within the next two years.

Celgene Corporation was a research-driven biopharmaceutical company which invested heavily in the discovery and development of innovative therapies that are now helping to improve the lives of tens of thousands of people worldwide. In considering legislative changes, I urge Congress to maintain many of the strong incentives that currently exist to encourage and support medical innovation.

Finally, because my mother died from a neurodegenerative disease, my son lives with insulin dependent diabetes, my daughter has autism, my brother is being treated for an incurable cancer, and all of us are severely impacted by the pandemic, this issue matters to me at a deeply personal level. I hope and believe that these incentives will lead to new treatments that society, and my family, will benefit from today and long after these medicines become generic drugs.

Thank you, and I look forward to answering your questions.