Testimony of Robert M. Davis, Chairman and CEO
Merck & Co., Inc.
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Chairman Sanders, Ranking Member Cassidy, and members of the Committee, thank you for the opportunity to be here with you today.

As the CEO of Merck, I am here to share the steps we are taking to ensure that American patients can afford our medicines, explain the barriers to our efforts that we encounter in the current pricing and access system, and offer concrete policy suggestions to both address these barriers and ensure our country continues to have the world's best climate for pharmaceutical innovation, so that Merck may discover and develop our next generation of lifesaving medicines and vaccines.

On behalf of everyone at Merck, I want to thank you for your interest in working to ensure that safe and effective medicines are broadly accessible to all Americans who need them. As people who go to work each day to help protect and improve the health of others, my Merck colleagues and I share your desire to make today's medicines more widely available—even as we work to discover tomorrow's best treatments.

At Merck, our mission is to use the power of leading-edge science to save and improve lives around the world. We develop and bring forward breakthrough medicines and vaccines and then make those treatments available to patients in the United States and worldwide. Based in Rahway, New Jersey, our company is one of the world's most advanced research-intensive biopharmaceutical companies, an organization at the forefront of providing innovative health solutions that advance the prevention and treatment of disease in people and animals.

With a focus on scientific discovery, our company exists to help solve the world's toughest medical challenges. Indeed, we have a long history of taking on urgent health needs, stretching back more than 130 years to Merck's founding in 1891. Over the decades, Merck has developed essential childhood vaccines; introduced the first protease inhibitor, which helped transform AIDS from a death sentence to a chronic disease; and developed the first statin, markedly reducing the negative health impacts of high cholesterol.

Merck's groundbreaking work on the treatment and prevention of cancer

Today, our journey of discovery continues. I have worked in the health care industry for the entirety of my 34-year career. I joined Merck 10 years ago in large measure because the company was on the precipice of its first approval for Keytruda, a novel programmed death receptor-1 (PD-1) inhibitor that had shown effectiveness in preventing cancer cells from suppressing the immune system. At the time, people close to me were battling cancer, and, unfortunately, they did not live long enough to benefit from this amazing discovery.

Following that first approval, Merck has demonstrated the efficacy of Keytruda in 39 indications, in 17 tumor types and 2 tumor-agnostic indications, and reached nearly 2 million patients battling many of the most widespread cancers afflicting Americans: non-small cell lung cancer, melanoma, head and neck cancer, and renal cell carcinoma. The impact of Keytruda and other recent treatment advances is difficult to overstate, with a recent American Cancer Society report finding that cancer mortality in the United States has fallen 33% from 1991 to 2021, representing an estimated 4 million Americans whose deaths have been averted.[1] And our work continues, as we advance Keytruda into even more tumor types and earlier stages of cancer.

Merck's breakthrough contributions in vaccine development have also played a critical role in the prevention of cancer. Our product Gardasil is the first-ever vaccine to guard against the human papillomavirus (HPV) that is the leading cause of nearly all cases of cervical cancer, which is the fourth most common cancer among women globally. A study of real world evidence published in the New England Journal of Medicine looking at Swedish girls and women between 10 and 30 years of age found a substantially reduced risk of invasive cervical cancer among those who had been fully vaccinated with Gardasil.[2] The American Cancer Society report found similar transformative public health outcomes in the United States, with a 65% decrease in cervical cancer rates in women in their early 20s, following the widespread adoption of HPV vaccines in the United States.[3]

These remarkable advances, and the others we are making in our many other oncology programs, have not come cheaply. Taking just Keytruda as an example, between 2011, when our focused Keytruda research program began, and 2023, Merck has invested $30 billion in our own internal clinical development efforts, $14 billion in research collaborations and acquisitions to further the study of Keytruda with other compounds, and $2 billion in capital expenditures to scale up our processes and facilities to manufacture the drug in large quantities. And we expect to invest another $18 billion in Keytruda clinical studies into the 2030s. This is likely now the largest and costliest pharmaceutical research and development program ever undertaken. Over 2,200 clinical trials have been publicly disclosed to study Keytruda alone and in conjunction with other compounds in pursuit of new lifesaving and life-extending applications for this revolutionary medicine.

Merck's substantial investments across our research and manufacturing efforts

And oncology is just one of Merck's many intense areas of discovery and development. Right now, we have nearly 20,000 researchers seeking breakthrough treatments for immune disorders, infectious diseases, Alzheimer's, cardiometabolic disease, and other ailments threatening the health of millions of people. To advance their critical work, we have invested more than $159 billion in research and development since 2010, including $30 billion in 2023 alone.

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[1] Siegel RL, Giaquinto AN, Jemal A. Cancer statistics, 2024. CA: A Cancer J Clin. https://doi.org/10.3322/caac.21820. Published Jan. 17, 2024. Accessed Feb. 3, 2024.
[2] Lei J, Ploner A, Elfstrom E, et al. HPV Vaccination and the Risk of Invasive Cervical Cancer. N Engl J Med 2020; 383:1340-1348. DOI: 10.1056/NENMoa1917338.
[3] Siegel RL, Miller KD, Wagle NS, et al. Cancer statistics, 2023. CA: A Cancer J Clin. https://doi.org/10.3322/caac.21763. Published Jan. 12, 2023. Accessed Feb. 3, 2024.

In support of these and other efforts, we are also making infrastructure investments, many of which are here in the United States. In fact, over the past five years, Merck has made capital investments across the United States totaling more than $10 billion, increasing our domestic capacity for R&D and manufacturing while creating hundreds of new jobs in our U.S. operations. For example, we've invested $3.6 billion in our Pennsylvania facilities since 2018, with plans to invest another $700 million this year. And in the past five years, we have invested $1.4 billion in our manufacturing facility in Elkton, Virginia—about two hours from here—to increase domestic production capacity for our Gardasil HPV vaccine.

We do not hesitate to make these investments because they are necessary to further Merck's mission: to serve patients—and not just the patients of today, but those who will need the new treatments and cures we have yet to discover. But we know that many Americans are struggling to afford health care, including prescription medicines, despite the best efforts of leaders in government, industry, academia, and the nonprofit community. Even though medicine costs are growing at the slowest rate in years, thanks in part to market competition, patients are too often being asked to pay more out-of-pocket for their medicines. And for some, that burden is simply too much to bear. As has often been observed, a lifesaving drug is not effective if the patient who needs that drug cannot afford it.

Thus, I am here today to share our perspective about the structural elements in our country's complex system of pricing, distribution, and insurance that have impeded Merck's efforts to bring our medicines to the American patients who need them. And I would humbly ask for your help and partnership in addressing these obstacles.

Merck's efforts to address patient access challenges

Merck has worked hard to help patients overcome access and affordability challenges. That work continues. We believe our company and our industry have a duty to act responsibly in our pricing practices and contribute to affordability solutions. That is why we supported changes to the Medicare Part D program to create an out-of-pocket cap and allow beneficiaries to pay their costs over time. And we have a history and heritage of responsible pricing. We are also committed to transparency in our pricing practices. Merck publicly discloses U.S. pricing data, including the average rebates and discounts we provide across our U.S. product portfolio to payers such as insurance companies, pharmacy benefit managers (PBMs), and the government.

We also have programs designed to help patients who cannot afford their medicines. To reduce patient out-of-pocket costs at the pharmacy counter, we provide coupons and other co-pay assistance for our products. Last year the value of this aid totaled $130 million. And through our support of a separate charitable organization that administers our patient assistance program, we provide free medicines to Americans of limited means who do not have insurance coverage or have some other hardship and cannot otherwise obtain their prescribed medications. In the past five years, this program has helped nearly 800,000 patients to obtain Merck medicines or vaccines free of charge, with an estimated value of $7.8 billion.

Structural challenges and Merck's suggested improvements for the U.S. system

But the reality is that Merck's efforts alone are far from sufficient. They do not and cannot address the underlying systemic and structural issues underpinning our system, which do not allow patients to benefit from the substantial discounts that manufacturers are providing on the medications they sell.

As more power and control has been consolidated into an ever-smaller number of vertically-consolidated players, their negotiating strength has increased dramatically. In Merck's efforts to contract with them, we continue to experience increasing pressure to provide even larger discounts, and the gap between list and net price continues to grow. But patients are not benefiting from the discounts being negotiated by PBMs. Instead, their insurers often base their cost-sharing on the list price, even when PBMs and insurance companies are paying a heavily discounted fraction of that price.

Our diabetes treatment Januvia is a great example of this phenomenon. Today, the weighted average net price for Januvia represents a 90% discount off its list price; with the price of Januvia being 33% lower than its price when we launched it in 2006. This is, in part, a result of significant discounts and rebates in a highly competitive market over the years. But these discounts and rebates are not being passed along to patients in a way that reduces their out-of-pocket costs.

Simply reducing our list prices is not a solution because patients often experience reduced access to their drugs when they are either not included on or are dropped from PBM and plan formularies. For example, in 2016, Merck introduced our Hepatitis C medicine, Zepatier, at a list price 42% below that of the standard of care at the time. Yet, we had difficulty getting plans and PBMs to add the product to their formularies. The situation did not improve in July 2018, when we further reduced the list price by 60% and found no increased uptake. More recent efforts by other manufacturers to offer products with lower lists prices have resulted in similarly poor PBM and plan coverage compared to their high list price competitors. Thus, lower list prices can result in reduced access for patients.

Rather than passing the steep savings they obtain through to patients to lower their out-of-pocket costs at the pharmacy counter, we understand that insurance plans retain them to cover overhead costs and reduce insurance premiums for all their insureds. When they do this, rather than reducing medicine costs for those that need them, it means sick people end up effectively subsidizing healthy people. This dynamic is contrary to the basic idea of insurance, which should use the premiums of healthy people to help fund the care of those who are struggling. This is yet another way in which our current system is fundamentally flawed.

From 2010 through 2023, Merck's annual average net price increase across our U.S. portfolio has been in the low- to mid-single digits. In 2017, our average net price actually declined nearly 2%. In 2022, the average discount for our medicines and vaccines was 40% off the list price. This money is flowing in part to middlemen, not to the innovative manufacturers that would reinvest that money to find tomorrow's cures. And, by and large, patients did not receive the

financial benefits of these substantial discounts. Instead, their out-of-pocket costs continue to rise.

Though the issues I have described are complex and impossible for one company—or even the pharmaceutical industry collectively—to address, legislative solutions may not be difficult to implement. If Congress were to require that other actors' revenue streams be delinked from the list price of a medicine, it would remove incentives for the system to favor high list prices. This would also ensure that less of the value in the system flows to these middlemen, who did not discover, develop, or produce the medicines for which they contract.

Another critically important fix is to require that the substantial savings provided by Merck and other manufacturers be passed through to patients to lower their out-of-pocket costs at the pharmacy counter, rather than allowing insurance plans to retain them. Reforms like these are necessary and will help provide long-term solutions for patients' out-of-pocket costs and ensure they can take advantage of the full breadth of innovative medicines available to keep them healthy and alleviate their suffering.

We firmly believe that it is possible to have a drug pricing system that incentivizes the discovery of new and important medicines and at the same time ensures patients can afford those lifesaving innovations. But reform of our current system is desperately needed to ensure that patients in the United States continue to have the greatest access, to the best medicines, faster than anywhere else in the world. I would encourage you to support legislative or administrative remedies that would address these systemic problems.

Fostering innovation alongside patient access solutions

These are exciting times in the biopharmaceutical industry and the wider world of health care. Decades of research investment are producing discoveries of increasing promise and impact. Life-threatening diseases like cancer are being conquered. Patients are living longer, healthier lives, even with serious conditions.

But let me be very clear: today's investments drive tomorrow's discoveries of breakthrough treatments. If we disrupt an ecosystem that incentivizes robust investments in research, we put at risk not only the foundation of American leadership in pharmaceutical development but also the health and lives of countless people who would have benefitted from future discoveries.

We do not have to go down that path. In fact, we have examples of efforts that are already working. For instance, the Medicare Part D program facilitates actual negotiation, effectively holding down costs and broadening patient access without threatening to injure or destroy the innovation ecosystem that fosters future treatment breakthroughs.

The most important positive contributions Merck makes in the world—impacting economies, health care systems, and the wellbeing of countless patients and their families—are pharmaceutical innovations that save and improve lives. Achieving such innovations requires us to invest billions of dollars a year in the often unsung work of thousands of brilliant researchers sitting at lab benches and striving, with all they have, to create transformative breakthroughs.

The odds are stacked against these scientists, but they keep trying, and we keep investing. Even with all the advantages of modern technology, discoveries are few and far between. And, even among those discoveries that spark clinical trials, nine out of ten compounds will fail.

Of course, our country needs to contain health care costs and reduce out-of-pocket costs to patients. And Merck is committed to being part of the solution. But we must pursue greater affordability and accessibility for medicines—and health care more broadly—in ways that preserve and strengthen our innovation ecosystem across academia, smaller biotech firms, larger pharmaceutical companies, government agencies, insurers, providers, and other stakeholders.

Ultimately, I believe we need to work together across these stakeholders to overcome the access and affordability challenges faced by today's patients without damaging our ability to innovate and discover new treatments for tomorrow's patients. Future treatment breakthroughs hinge on what we do now. We must hold onto a U.S. pharmaceutical market that is free, competitive, and predictable, one that encourages and rewards investment, one that drives the American economy and creates jobs, and one that continues to deliver innovation and new treatment discoveries.

I am here today to pledge our support and cooperation in this effort and other measures to help Americans live longer, healthier lives with improved access to effective and affordable drug treatments, and in ways that protect incentives for future innovation.

Thank you for your time and your consideration of these perspectives, and thank you again for the opportunity to share them with you today.