

**TESTIMONY OF KENNETH C. FRAZIER, CEO**  
**Merck & Co., Inc.**  
**Before the United States Senate Committee on Finance**  
**Drug Pricing in America: A Prescription for Change, Part II**  
**February 26, 2019**

Mr. Chairman, Senator Wyden, and members of the Committee, thank you for the opportunity to appear today. Merck's mission is to save and improve lives around the world by bringing forward breakthrough medicines and vaccines, and ensuring they are available and affordable to patients who need them.

Merck is a science-based company that exists to help solve the world's most vexing medical challenges. We have a long history of doing this, from the development of most of the common childhood vaccines, to bringing the first protease inhibitor to patients, turning AIDS from a death sentence to a chronic disease, to developing the first statin, which led to significant reductions in the negative health effects of high cholesterol. This legacy of invention continues today.

Research is at the core of who we are and what we do. Last year, Merck invested nearly \$10 billion in research and development toward our mission of preventing, treating, and curing disease, and since 2010 we've invested nearly \$70 billion in these efforts. Our more than 12,000 researchers are focused on cancer, infectious diseases, and Alzheimer's, as well as other major health challenges that affect large numbers of people around the world. For our breakthrough immuno-oncology drug Keytruda alone we have over 900 clinical trials under way.

In pursuit of these efforts, we are also investing significantly in infrastructure here in the United States. We have invested more than \$5 billion in the last five years, and we plan to invest \$9 billion more over the next few years to increase manufacturing capacity and open two new discovery research centers.

Our mission is to go where the science leads us, which means we don't allocate resources only to addressing diseases in wealthy countries; we focus our efforts on conditions that significantly impact people living all over the world.

For instance, we are proud to have deployed 70,000 doses of our experimental Ebola vaccine in the Democratic Republic of the Congo, working in partnership with the Centers for Disease Control and Prevention, the Biomedical Advanced Research and Development Authority, and the Department of Health and Human Services. For efforts such as this there is no commercial opportunity, but we pursue them because these are the challenges that Merck was created to tackle.

At the end of the day we do all of this to serve patients. We understand that patients are having a harder and harder time affording their health care, including their prescription medicines. As a result of robust negotiation and competition in the marketplace, medicine costs are growing at the slowest rate in years, but the system is still not working for patients who are too often being

asked to pay more out-of-pocket due to the complex system of pricing, distribution, and insurance. I am here today to suggest a few ways that we can address this problem together.

First, we want to be clear that our industry has a duty to be responsible in our pricing practices and contribute to solutions that address the affordability problems facing patients. We have all heard the egregious examples of irresponsible behavior. At Merck, we have a history of responsible pricing. To help increase transparency about our pricing practices, we publicly disclose information about our prices in the U.S. and the rebates and discounts we provide to payers – including insurers, pharmacy benefit managers, and the government. Last year, we pledged that we will not increase our average net prices for our portfolio by more than the rate of inflation annually.

From 2010 to 2017, Merck's average net price increase across our portfolio each year has been in the low to mid-single digits. In fact, our average net price declined in 2017 by almost 2 percent. In 2017, the average discount for our medicines and vaccines was more than 45 percent lower than the list price. Despite these very large discounts, patients do not see a commensurate benefit. In fact, patient out-of-pocket costs continue to rise, and patients are being asked to shoulder more of their drug costs than other health care services.

Second, we must ensure that patients get the benefit of the large rebates and discounts that manufacturers are paying to PBMs and insurance companies.

The incentives in the current system are badly misaligned. As a result, the current system of drug competition that depends on rebating is not working for patients. The growing gap between our list prices and our net prices that results from rebating has created incentives for supply chain entities to favor products with higher list prices. For instance, in 2016, we introduced our hepatitis C therapy, Zepatier, at a list price that was 42% below the price of the therapy that was the standard of care. However, due to the misaligned incentives in the supply chain that create a preference for higher priced products, we had difficulty gaining access for patients in certain market segments.

This kind of misalignment can have a significant negative impact on patients because their cost-sharing is often based on the list price of a drug, even when insurance companies and PBMs are paying a fraction of that price. Our current system that incentivizes high list prices and large rebates as a mechanism to keep insurance premiums low means that sick patients are essentially subsidizing healthy patients. In this way, our insurance system is broken. We urge you to support action to make sure that all patients benefit from the discounts we make available.

Third, we can significantly reduce spending on pharmaceuticals, especially for patients, by ensuring that we have a viable market for biosimilars in the United States. We believe, like with traditional small molecule medicines, generic competition after a reasonable period of exclusivity will create headroom for patients to afford the newest, most innovative medicines. Research shows that generics and biosimilars are expected to drive savings of \$105 billion through 2022 in the U.S.<sup>1</sup>

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<sup>1</sup> IQVIA Institute for Human Data Science. Medicine use and spending in the U.S.: A review of 2017 and outlook to 2022. <https://www.iqvia.com/institute/reports/medicine-use-and-spending-in-the-us-review-of-2017-outlook-to-2022>. Published April 19, 2018. Accessed April 2018.

However, we share the concerns expressed by FDA Commissioner Gottlieb regarding the challenges biosimilars have experienced in penetrating the market. Merck introduced a biosimilar to the market 18 months ago at a 35 percent discount to the originator product, yet we have captured only a tiny fraction of the market. In general, biosimilars competition thus far has resulted in moderation of prices, but actual utilization of the biosimilars remains modest at best. We fear that an environment where market entry of biosimilars brings value to the market, but little or none of that value accrues to the biosimilar, will not be sustainable.

Therefore, we urge Congress to pursue policies to encourage and support biosimilar uptake and utilization in order to realize these potential savings for the system and patients. These could include reduced cost sharing in Medicare Part B.

Fourth, we believe that prices can more align with a drug's value when manufacturers and payers are able to negotiate innovative contracts that base payment on a drug's benefits. Manufacturers should be rewarded based on the value that our therapies deliver. When we developed our breakthrough immuno-oncology treatment Keytruda, we incorporated a biomarker where clinically appropriate so that we could identify those patients most likely to benefit, but this is not always the case. We did this because we believe in giving the right medicine to the right patient at the right time. This is important both for therapeutic and economic reasons. If patients regularly take our medicines as they are prescribed, we are prepared to stand behind their effectiveness.

Moving to a system where we are reimbursed for the value our medicines provide would be revolutionary. Yet there remain major regulatory and operational obstacles to value-based payment and contracting in the commercial and public markets, which we urge Congress to address.

Fifth, we support efforts to encourage generic competition. A version of Chairman Grassley's CREATES Act could make some needed reforms to encourage generic competition, and there are likely other policies we should consider as well to ensure there is no inappropriate gaming of the system.

We also support the idea of eliminating the use of drug company coupons in cases where a brand name drug now has generic competition. This slows the use of generics and violates the spirit of the Hatch-Waxman drug price competition law.

Finally, we would also like to work with the Committee to find ways to end the price gouging pursued by those who jack up the prices of off-patent drugs that have no competition. These high prices hurt patients and do not create incentives for the kind of cutting edge research we pursue.

These six changes could bring real relief to patients while preserving the incentives that allow us to invest billions in developing new medicines. These are exciting times, when decades of investment in scientific research are yielding life-changing discoveries. But it is the investment of today that fuels the innovations of tomorrow, and if we damage the ecosystem that drives

those investments, we'll never know what we could have achieved for the patients we are all here to serve.

The single most important contribution that we make at Merck – to economies, to health care, and to individual patients and their families – is to continue making the necessary costly and long-term investments in R&D and persuading thousands of brilliant researchers to sit at a lab bench and try to create something transformative – despite the overwhelming odds that their efforts will not succeed, since 9 out of 10 compounds that even start clinical trials will fail.

The solutions to health care spending and out-of-pocket costs for patients must be achieved in a way that provides the balance necessary for innovation to occur. The innovation ecosystem includes academia, small biotechnology companies, large pharmaceutical companies, government, and patients and providers. It is incumbent on all of us to solve the affordability challenges of today's patients without compromising our ability to invent for tomorrow's patients.

I'd like to end on a personal note. My mother died when I was a child and my siblings and I were raised by my dad who worked as a janitor in North Philadelphia. He was a giant in my life and it was devastating when Alzheimer's took him away from me and my family.

Last year, after spending many years and over a billion dollars, Merck had to end development of a promising new Alzheimer's therapy because it simply didn't work. Yet we continue on, seeking better approaches. And I truly believe Merck or one of the other companies at this table can and will find a medicine that will ensure that no one will have to experience the pain of seeing a loved one taken from them in this way.

But, our success depends on having a U.S. market that is free, competitive, and predictable. The changes I've discussed today have the potential to vastly improve that market and help patients survive and thrive without financial hardship. I am here to pledge our cooperation with you for creating such changes.

Thank you.